RULES
OF
DEPARTMENT OF HEALTH
TENNESSEE MEDICAL LABORATORY BOARD
DIVISION OF HEALTH RELATED BOARDS

CHAPTER 1200-6-3
GENERAL RULES GOVERNING MEDICAL LABORATORIES

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1200-6-3-.01 DEFINITIONS. As used in this chapter of Rules the following terms and acronyms shall have the following meanings ascribed to them:

(1) ASTC - Ambulatory Surgical Treatment Center, specifically any institution, place or building devoted primarily to the maintenance and operation of a facility for the performance of surgical procedures or any facility in which a medical or surgical procedure is utilized to terminate a pregnancy and is licensed by the Tennessee Board for Licensing Health Care Facilities under Rule 1200-8-10.

(2) Anatomic laboratory - Any medical laboratory performing only the biophysical examination of specimens pertaining to the clinical specialty of pathology, to include histopathology, oral pathology, and cytopathology. The examination of these specimens taken from the human body are performed to obtain information for diagnosis, prophylaxis, or treatment or where any examination, determination or test is made of any sample used as a basis for health advice, or where any sample is collected for the purpose of transfusion or processing of blood or blood fractions, or the training of medical laboratory personnel. Compliance with Rule 1200-6-1-.20 is required to be the director of an anatomic laboratory.

(3) Authorized person - A physician or intern or resident in an American Medical Association approved training program or a duly licensed optometrist or a duly licensed dentist or a duly licensed chiropractic physician or other health care professional legally permitted to submit to a medical laboratory a written request for tests appropriate to that professional's practice or a law enforcement officer acting in accordance with T.C.A. § 55-10-406.

(4) Board - The Tennessee Medical Laboratory Board.

(5) CLIA - The Clinical Laboratory Improvement Amendments as found in 42 CFR 493.

(6) CMS - The Centers for Medicare and Medicaid Services of the U.S. Department of Health and Human Services.

(7) Center for Disease Control (CDC) - The United States Center for Disease Control, headquartered in Atlanta, GA.

(Rule 1200-6-3-.01, continued)

(8) Clinical Laboratory - see Medical Laboratory.

(9) Code of Federal Regulations (CFR) - The documents that detail under Title 42, Chapter IV Part 493, the Laboratory Requirements under CLIA, and under Title 21, Parts 600 to 799, the Food and Drug Requirements.

(10) Condition - A specific requirement from the Board's rules that must be met for continued possession of a license to operate a medical laboratory in Tennessee. Unmet conditions of compliance with the Board's rules can result in harm to patients or facility personnel.

(11) Condition Level Deficiency - A significant deficiency of non-compliance with a rule. A deficiency that must be corrected before a license is continued, issued or is renewed.

(12) Days - Calendar days unless otherwise designated.

(13) Department - The Department of Health, State of Tennessee.

(14) FDA - The U.S. Food and Drug Administration.

(15) HCF - The Department of Health, Division of Health Care Facilities.

(16) HHS - The U.S. Department of Health and Human Services.

(17) Human Leukocyte Antigens (HLA) - Identification of the human histocompatibility complex antigens on the surface of nucleated cells.

(18) Independent Lab - A medical laboratory performing patient tests that is independent of both attending and consulting physician's offices and independent of a hospital also known as a reference laboratory.

(19) Manufacturer's instructions - Information found on the FDA approved product label.

(20) May - Discretionary.

(21) Medical Laboratory - Any institution, building, or place in which operations and procedures for the microbiological, serological, chemical, hematological, immunohematological, or biophysical examination of specimens taken from the human body are performed to obtain information for diagnosis, prophylaxis, or treatment or where any examination, determination, or test is made on any sample used as a basis for health advice, or where any sample is collected for the purpose of transfusion or processing of blood fractions, or for the training of medical laboratory personnel.

(22) Must - Mandatory.

(23) NCCLS - National Committee of Clinical Laboratory Standards.

(24) Office for the Medical Laboratory Board - The Office responsible for laboratory facility licensure.

(25) Performance Improvement (PI) - An ongoing process encompassing all facets of the laboratory or collection station technical and nontechnical functions at all locations/sites where testing is performed.

(26) Plan of Correction - The laboratory's or collection station's response to any citation of non-compliance with regulations. The Plan of Correction must be reasonable, contain specific actions to correct deficiencies with estimated correction dates and contain the signature of the Laboratory Director or his authorized Designee or collection station director or his authorized designee.

(Rule 1200-6-3-.01, continued)

(27) Point of Care Laboratory Testing - Those tests performed by health care professionals, not licensed by this chapter, upon approval by the board, provided that the testing is performed outside the duly licensed laboratory, and under the auspices of a laboratory required to be licensed by the division of health care facilities in the department of health, pursuant to this chapter.

(28) Physician Office Laboratory - A laboratory operated by a duly licensed physician for the sole purpose of testing samples collected from their own patients.

(29) Reference Laboratory - A medical laboratory performing patient tests that is independent of both attending and consulting physician's offices and independent of a hospital also known as an independent laboratory.

(30) Shall - Mandatory.

(31) Standard - A specific requirement from the state rules that must be met for continued possession of a license to operate a medical laboratory or collection station in Tennessee. Unmet standards of compliance usually reflect unsatisfactory performance of laboratory or collection station operations according to accepted standards of medical laboratory practice.

(32) Standard Level Deficiency - A deficiency of non-compliance with a regulation for which a license would be issued or renewed, provided an acceptable plan of correction with an estimated completion date has been submitted and approved.

(33) Statement of Deficiencies - An official notification of non-compliance with one (1) or more regulatory requirements.

(34) Unsatisfactory Proficiency Testing Performance - Failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event.

(35) Unsuccessful Proficiency Testing Performance - Failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two (2) consecutive or two (2) of three (3) consecutive testing events.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-103, 68-29-105, 63-29-111, 68-29-116, and Public Acts of 2002, Chapter 623.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Amendment filed December 14, 1981; effective January 28, 1982. Amendment filed June 30, 1987; effective August 14, 1987. Repeal and new rule filed May 15, 1990; effective June 29, 1990. Amendment filed November 30, 1990; effective January 14, 1991. Amendment filed February 21, 1991; effective April 7, 1991. Repeal filed May 3, 1995; effective July 17, 1995. New rule filed January 7, 1997; effective March 23, 1997. Repeal and new rule filed June 18, 2002; effective September 1, 2002. Amendment filed May 23, 2003; effective August 6, 2003.*

1200-6-3-.02 LICENSING PROCEDURES.

(1) Applications

(a) An application for a medical laboratory license shall be made under oath, by the owner and director of the medical laboratory or public official responsible for the operation of a city or county medical laboratory or institution that contains a medical laboratory, upon forms provided by the Board.

(b) All laboratories performing tests must file a separate application for each laboratory address.

(Rule 1200-6-3-.02, continued)

(c) Laboratories within a hospital that are located in contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

(d) Each application shall include, in alphabetical order, a roster of all personnel currently employed in the laboratory, the classification/category in which the employee functions and is licensed, license number, expiration date and social security number. This shall include all medical laboratory directors, consultants, supervisors and testing personnel.

(e) The application will be returned to the applicant if it is incomplete or requires correction.

(f) After submission of the completed application, the laboratory or collection station may be issued a letter of temporary license which shall be valid for a period of not longer than three (3) months from the date the application is received by the Board. This temporary license will allow the laboratory to perform testing and allow the collection station to collect specimens until an on-site inspection is conducted and a determination is made whether the laboratory or collection station is in compliance. The laboratory shall be fully operational, including but not limited to the reporting of patient results, at the time of the on-site inspection. The collection station shall be fully operational at the time of the on-site inspection. If the laboratory or collection station is found to be in compliance, it shall be issued a permanent license, provided all other requirements for licensure have been met.

(2) License - Issued

(a) A license shall be issued authorizing the performance of one (1) or more medical laboratory specialties or subspecialties, the location of testing, the name of the laboratory director and type of ownership.

(b) A license shall be issued authorizing the collection of specimens, the location of collection, the name of the physician and type of ownership.

(c) A license shall be valid only in the hands of the person or persons to whom it is issued and shall not be the subject of sale, assignment, or transfer, voluntary or involuntary, nor shall a license be valid for any premises other than those for which issued.

(d) The license shall be displayed at all times in a prominent place where it may be viewed by the public.

(3) Expiration and Renewal of License

(a) The license to operate the laboratory or collection station shall expire annually on the anniversary of the date that the license was originally issued.

(b) Methods of Renewal

1. Internet Renewals - Laboratories and collection stations may apply for renewal and pay the necessary fees via the Internet. The application to renew can be accessed at:

www.tennesseeanytime.org

2. Paper Renewals - For laboratories or collection stations who have not renewed their license online via the Internet, a renewal application form will be mailed to each laboratory and collection station licensed by the Board at least sixty (60) days prior to the expiration date to the last address provided to the Board. Failure to receive such

(Rule 1200-6-3-.02, continued)

notification does not relieve the laboratory or collection station from the responsibility of meeting all requirements for renewal.

3. Rule 1200-6-3-.02(1)(a)-(e) applies for renewals.

(4) Fees - The fees established by the Board pursuant to the Tennessee Medical Laboratory Act (T.C.A. §§ 68-29-101, et seq.) for licensure are as follows:

(a)	Initial Laboratory Application Fee - This fee is nonrefundable.	$1000.00
(b)	Laboratory License Renewal Fee - To be paid annually by all licensees.	$1000.00
(c)	Late Laboratory License or Collection Station Renewal Penalty Fee - To be paid when a licensee fails to timely renew annual license.	$ 500.00
(d)	Annual State Regulatory Fee - To be paid by all licensees.	$ 5.00
(e)	Replacement License (other than 1200-6-3-.03) when lost or misplaced.	$ 50.00
(f)	Initial Collection Station Application Fee	$ 700.00
(g)	Collection Station Renewal Fee	$ 700.00

(5) Fees may be paid in the following manner:

(a) All fees paid by money order, certified, personal, or corporate check must be submitted to the Board's Administrative Office and made payable to the Tennessee Medical Laboratory Board.

(b) Fees may be paid by Division-approved credit cards or other Division-approved electronic methods.

Authority: *T.C.A. §§4-3-1011, 4-5-202, 4-5-204, 68-29-105, 68-29-111, 68-29-112, 68-29-113, 68-29-114, and 68-29-115.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Amendment filed June 30, 1987; effective August 14, 1987. Amendment filed February 21, 1991; effective April 7, 1991. Repeal and new rule filed January 7, 1997; effective March 23, 1997. Amendment filed August 31, 2001; effective November 14, 2001. Repeal and new rule filed June 18, 2002; effective September 1, 2002. Amendment filed July 8, 2004; effective September 21, 2004.*

1200-6-3-.03 CHANGE IN LOCATION, DIRECTOR, OWNER, SUPERVISOR OR TESTING IN A MEDICAL LABORATORY.

(1) It shall be the responsibility of the owner to notify the Department in writing of a change in the location, director, owners or supervisor of the laboratory within fifteen (15) days of the actual change. A replacement license shall be issued by the Department at no cost for the remainder of the calendar year for a new location, director, or owner, provided that in the case of change of directors, the new director is already licensed or is eligible for licensure as a medical laboratory director under the Medical Laboratory Act and the regulations promulgated thereunder.

(2) It shall be the responsibility of the owner to notify the Department in writing in order to add a specialty or subspecialty not presently authorized by the facility's license prior to the commencement of testing and reporting patient test results. The Department may conduct an on-site inspection prior to the issuance of authorization for the specialty or subspecialty. A replacement license which includes new specialty or subspecialty shall be issued by the Department at no cost to the facility.

(Rule 1200-6-3-.03, continued)

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-105, 68-29-112, and 68-29-114.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Repeal filed May 3, 1995; effective July 17, 1995. New rule filed January 7, 1997; effective March 23, 1997. Repeal and new rule filed June 18, 2002; effective September 1, 2002.*

1200-6-3-.04 INSPECTIONS - REPORTS.

(1) Biennial Inspections of Licensed Laboratories

(a) The Board or its Designee will conduct announced and/or unannounced inspections on at least a biennial basis of any laboratory at any time during its hours of operation to assess compliance with the applicable requirements.

(b) It is board policy that regular biennial inspections be unannounced.

(c) Written reports of inspection results will be submitted to the medical laboratory director within ten (10) working days of the on-site visit.

(d) The medical laboratory director must respond to any deficiencies cited with a written plan of correction that includes estimated correction dates, within ten (10) working days of the receipt of the statement of deficiencies.

(2) Inspection for Initial License - The laboratory shall be issued an initial license only after an on-site inspection is conducted and the laboratory has no deficiencies, or has submitted an acceptable plan of correction for all standard level deficiencies. All condition level deficiencies must be corrected before the laboratory shall be issued a license.

Authority: *T.C.A. §§4-5-204, 4-5-204, 68-29-105, 68-29-106, and 68-29-113.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Amendment filed December 14, 1981; effective January 28, 1982. Repeal and new rule filed January 7, 1997; effective March 23, 1997. Repeal and new rule filed June 18, 2002; effective September 1, 2002.*

1200-6-3-.05 LICENSURE DISCIPLINE, ASSESSMENT OF COSTS, AND SUBPOENAS.

(1) Upon a finding by the Board that a licensee has violated any provision of the Tennessee Medical Laboratory Act (T.C.A. §§ 68-29-101, et seq.) or the rules promulgated pursuant thereto, the Board may impose any of the following actions separately or in any combination which is deemed appropriate to the offense:

(a) Private Censure - This is a written action issued by the Board to the licensee for minor infractions of these rules. It is informal and advisory in nature and does not constitute a formal disciplinary action.

(b) Public Censure or Reprimand - This is a formal disciplinary action consisting of a written admonishment issued by the Board to a licensee for one (1) time and less severe infractions.

(c) Probation - This is a formal disciplinary action which places a licensee on close scrutiny for a fixed period of time. This action may be combined with conditions which must be met before probation will be lifted and/or which restrict the licensee's activities during the probationary period.

(d) Licensure Suspension - This is a formal disciplinary action which suspends a licensee's right to operate a medical laboratory for a fixed period of time. It contemplates the reentry of the licensee into operation under the license previously issued.

(e) Licensure Revocation - This is the most severe form of disciplinary action which removes a licensee from the operation of a medical laboratory and terminates the license previously issued. If revoked, it relegates the violator to the status he or she possessed prior to application for licensure. However, the Board may in its discretion allow the reinstatement of a revoked license upon conditions and after a period of time it deems appropriate. No petition for reinstatement and no new application for licensure from a medical laboratory whose license was revoked shall be considered prior to the expiration of at least one (1) year unless otherwise stated in the Board's revocation Order.

(f) Once ordered, probation, suspension, revocation, or any other condition of any type of disciplinary action may not be lifted unless and until the licensee petitions, pursuant to paragraph (2) of this rule, and appears before the Board after the period of initial probation, suspension, revocation, or other conditioning has run and all conditions placed on the probation, suspension, revocation, have been met.

(2) Order of Compliance - This procedure is a necessary adjunct to previously issued disciplinary orders and is available only when a petitioner has completely complied with the provisions of a previously issued disciplinary order, and wishes or is required to obtain an order reflecting that compliance.

(a) The Board will entertain petitions for an Order of Compliance as a supplement to a previously issued order upon strict compliance with the procedures set forth in subparagraph (b) in only the following three (3) circumstances:

1. When the petitioner can prove compliance with all the terms of the previously issued order and is seeking to have an order issued reflecting that compliance; or

2. When the petitioner can prove compliance with all the terms of the previously issued order and is seeking to have an order issued lifting a previously ordered suspension or probation; or

3. When the petitioner can prove compliance with all the terms of the previously issued order and is seeking to have an order issued reinstating a license previously revoked.

(b) Procedures

1. The petitioner shall submit a Petition for Order of Compliance, as contained in subparagraph (c), to the Board's Administrative Office that shall contain all of the following:

(i) A copy of the previously issued order; and

(ii) A statement of which provision of subparagraph (a) the petitioner is relying upon as a basis for the requested order; and

(iii) A copy of all documents that prove compliance with all the terms or conditions of the previously issued order. If proof of compliance requires testimony of an individual(s), including that of the petitioner, the petitioner must submit signed statements from every individual the petitioner intends to rely upon attesting, under oath, to the compliance. The Board's consultant and administrative staff, in their discretion, may require such signed statements to be notarized. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, the petition.

(Rule 1200-6-3-.05, continued)

2. The Board authorizes its consultant and administrative staff to make an initial determination on the petition and take one of the following actions:

   (i) Certify compliance and have the matter scheduled for presentation to the Board as an uncontested matter; or

   (ii) Deny the petition, after consultation with legal staff, if compliance with all of the provisions of the previous order is not proven and notify the petitioner of what provisions remain to be fulfilled and/or what proof of compliance was either not sufficient or not submitted.

3. If the petition is presented to the Board the petitioner may not submit any additional documentation or testimony other than that contained in the petition as originally submitted.

4. If the Board finds that the petitioner has complied with all the terms of the previous order an Order of Compliance shall be issued.

5. If the petition is denied either initially by staff or after presentation to the Board and the petitioner believes compliance with the order has been sufficiently proven the petitioner may, as authorized by law, file a petition for a declaratory order pursuant to the provisions of T.C.A. § 4-5-223 and rule 1200-10-1-.11.

(c) Form Petition

Petition for Order of Compliance
Tennessee Medical Laboratory Board

Petitioner's Name: _____
Petitioner's Mailing Address: _____
_____
_____
Petitioner's E-Mail Address: _____
Telephone Number: _____

Attorney for Petitioner: _____
Attorney's Mailing Address: _____
_____
_____
Attorney's E-Mail Address: _____
Telephone Number: _____

The petitioner respectfully represents, as substantiated by the attached documentation, that all provisions of the attached disciplinary order have been complied with and I am respectfully requesting: (circle one)

1. An order issued reflecting that compliance; or

2. An order issued reflecting that compliance and lifting a previously ordered suspension or probation; or

3. An order issued reflecting that compliance and reinstating a license previously revoked.

(Rule 1200-6-3-.05, continued)

Note - You must enclose all documents necessary to prove your request including a copy of the original order. If any of the proof you are relying upon to show compliance is the testimony of any individual, including yourself, you must enclose signed statements from every individual you intend to rely upon attesting, under oath, to the compliance. The Board's consultant and administrative staff, in their discretion, may require such signed statements to be notarized. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, this petition.

Respectfully submitted this the _____ day of _____, 20____.

_____
Petitioner's Signature

(3) Order Modifications - This procedure is not intended to allow anyone under a previously issued disciplinary order, to modify any findings of fact, conclusions of law, or the reasons for the decision contained in the order. It is also not intended to allow a petition for a lesser disciplinary action. All such provisions of Board orders were subject to reconsideration and appeal under the provisions of the Uniform Administrative Procedures Act (T.C.A. §§ 4-5-301, et seq.). This procedure is not available as a substitute for reconsideration and/or appeal and is only available after all reconsideration and appeal rights have been either exhausted or not timely pursued. It is also not available for those who have accepted and been issued a reprimand.

(a) The Board will entertain petitions for modification of the disciplinary portion of previously issued orders upon strict compliance with the procedures set forth in subparagraph (b) only when the petitioner can prove that compliance with any one or more of the conditions or terms of the discipline previously ordered is impossible. For purposes of this rule the term "impossible" does not mean that compliance is inconvenient or impractical for personal, financial, scheduling or other reasons.

(b) Procedures

1. The petitioner shall submit a written and signed Petition for Order Modification on the form contained in subparagraph (c) to the Board's Administrative Office that shall contain all of the following:

(i) A copy of the previously issued order; and

(ii) A statement of why the petitioner believes it is impossible to comply with the order as issued; and

(iii) A copy of all documents that proves that compliance is impossible. If proof of impossibility of compliance requires testimony of an individual(s), including that of the petitioner, the petitioner must submit signed and notarized statements from every individual the petitioner intends to rely upon attesting, under oath, to the reasons why compliance is impossible. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, the petition.

2. The Board authorizes its consultant and administrative staff to make an initial determination on the petition and take one of the following actions:

(i) Certify impossibility of compliance and forward the petition to the Office of General Counsel for presentation to the Board as an uncontested matter; or

(Rule 1200-6-3-.05, continued)

(ii) Deny the petition, after consultation with legal staff, if impossibility of compliance with the provisions of the previous order is not proven and notify the petitioner of what proof of impossibility of compliance was either not sufficient or not submitted.

3. If the petition is presented to the Board the petitioner may not submit any additional documentation or testimony other than that contained in the petition as originally submitted.

4. If the petition is granted a new order shall be issued reflecting the modifications authorized by the Board that it deemed appropriate and necessary in relation to the violations found in the previous order.

5. If the petition is denied either initially by staff or after presentation to the Board and the petitioner believes impossibility of compliance with the order has been sufficiently proven the petitioner may, as authorized by law, file a petition for a declaratory order pursuant to the provisions of T.C.A. § 4-5-223 and rule 1200-10-1-.11.

(c) Form Petition

Petition for Order Modification
Tennessee Medical Laboratory Board

Petitioner's Name: _____
Petitioner's Mailing Address: _____
_____
_____
Petitioner's E-Mail Address: _____
Telephone Number: _____

Attorney for Petitioner: _____
Attorney's Mailing Address: _____
_____
_____
Attorney's E-Mail Address: _____
Telephone Number: _____

The petitioner respectfully represents that for the following reasons, as substantiated by the attached documentation, the identified provisions of the attached disciplinary order are impossible for me to comply with:

_____
_____
_____
_____

Note – You must enclose all documents necessary to prove your request including a copy of the original order. If any of the proof you are relying upon to show impossibility is the testimony of any individual, including yourself, you must enclose signed and notarized statements from every individual you intend to rely upon attesting, under oath, to the reasons why compliance is impossible. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, this petition.

Respectfully submitted this the _____ day of _____, 20____.

_____

Petitioner's Signature

(4) The provisions of the Uniform Administrative Procedures Act, T.C.A. §§ 4-5-301, et seq., shall govern the hearing and judicial review of all disciplinary proceedings.

(5) Assessment of costs in disciplinary proceedings shall be as set forth in T.C.A. §§ 63-1-144 and 68-29-136.

(6) Subpoenas

(a) Purpose - Although this rule applies to persons and entities other than medical laboratories, it is the Board's intent as to medical laboratories that they be free to operate without fear that such operation or its documentation will be unduly subjected to scrutiny outside the profession. Consequently, balancing that intent against the interest of the public and patients to be protected against substandard care and activities requires that persons seeking to subpoena such information and/or materials must comply with the substance and procedures of these rules.

It is the intent of the Board that the subpoena power outlined herein shall be strictly proscribed. Such power shall not be used by the Division or Board investigators to seek other incriminating evidence against medical laboratory personnel when the Division or Board does not have a complaint or basis to pursue such an investigation. Thus, unless the Division or its investigators have previously considered, discovered, or otherwise received a complaint from either the public or a governmental entity, then no subpoena as contemplated herein shall issue.

(b) Definitions - As used in this chapter of rules the following words shall have the meanings ascribed to them:

1. Probable Cause

(i) For investigative subpoenas shall mean that probable cause, as defined by case law at the time of request for subpoena issuance is made, exists that a violation of the Medical Laboratory Practice Act or rules promulgated pursuant thereto has occurred or is occurring and that it is more probable than not that the person(s), or items to be subpoenaed possess or contain evidence which is more probable than not relevant to the conduct constituting the violation.

(ii) The utilization of the probable cause evidentiary burden in proceedings pursuant to this rule shall not in any way, nor should it be construed in any way to establish a more restrictive burden of proof than the existing preponderance of the evidence in any civil disciplinary action which may involve the person(s) or items that are the subject of the subpoena.

2. Presiding Officer - For investigative subpoenas shall mean any elected officer of the Board, or any duly appointed or elected chairperson of any panel of the Board.

(c) Procedures

1. Investigative Subpoenas

(i) Investigative Subpoenas are available only for issuance to the authorized representatives of the Tennessee Department of Health, its investigators and its legal staff.

(ii) An applicant for such a subpoena must either orally or in writing notify the Board's Unit Director of the intention to seek issuance of a subpoena. That notification must include the following:

(I) The time frame in which issuance is required so the matter can be timely scheduled; and

(II) A particular description of the material or documents sought, which must relate directly to an ongoing investigation or contested case, and shall, in the instance of documentary materials, be limited to the records of the patient or patients whose complaint, complaints, or records are being considered by the Division or Board.

(III) In no event shall such subpoena be broadly drafted to provide investigative access to medical laboratory records of other patients who are not referenced in a complaint received from an individual or governmental entity, or who have not otherwise sought relief, review, or Board consideration of any medical laboratory personnel's conduct, act, or omission; and

(IV) Whether the proceedings for the issuance is to be conducted by physical appearance or electronic means; and

(V) The name and address of the person for whom the subpoena is being sought, or who has possession of the items being subpoenaed.

(iii) The Board's Unit Director shall cause the following to be done:

(I) In as timely a manner as possible arrange for either an elected officer of the Board or any duly appointed or elected chairperson of any panel of the board to preside and determine if issuing the subpoena should be recommended to the full board; and

(II) Establish a date, time and place for the proceedings to be conducted and notify the Presiding Officer, the applicant and the court reporter; and

(III) Maintain a complete record of the proceedings including an audio tape in such a manner as to:

I. Preserve a verbatim record of the proceeding; and

II. Prevent the person presiding over the proceedings and/or signing the subpoena from being allowed to participate in any manner in any resulting disciplinary action of any kind, formal or informal, which involves either the person or the documents or records for which the subpoena was issued.

(iv) The Proceedings

(I) The applicant shall do the following:

I. Provide for the attendance of all persons whose testimony is to be relied upon to establish probable cause; and

II. Produce and make part of the record copies of all documents to be utilized to establish probable cause; and

III. Obtain, complete and provide to the Presiding Officer a subpoena which specifies the following:

A. The name and address of the person for whom the subpoena is being sought or who has possession of the items being subpoenaed; and

B. The location of the materials, documents or reports for which production pursuant to the subpoena is sought if that location is known; and

C. A brief, general description of any materials, documents or items to be produced pursuant to the subpoena; and

D. The date, time and place for compliance with the subpoena.

IV. Provide the Presiding Officer testimony and/or documentary evidence which, in good faith, the applicant believes is sufficient to establish that probable cause exists for issuance of the subpoena as well as sufficient proof that all other reasonably available alternative means of securing the materials, documents or items have been unsuccessful.

(II) The Presiding Officer shall do the following:

I. Be selected only after assuring the Board's Unit Director that he or she has no prior knowledge of or any direct or indirect interest in or relationship with the person(s) being subpoenaed and/or the licensee who is the subject of the investigation; and

II. Commence the proceedings and swear all necessary witnesses; and

III. Hear and maintain the confidentiality, if any, of the evidence presented at the proceedings and present to the full board only that evidence necessary for an informed decision; and

IV. Control the manner and extent of inquiry during the proceedings and be allowed to question any witness who testifies; and

V. Determine, based solely on the evidence presented in the proceedings, whether probable cause exists and if so, make such recommendation to the full Board; and

VI. Not participate in any way in any other proceeding whether formal or informal, which involves the matters, items or person(s) which are the subject of the subpoena. This does not preclude the Presiding Officer from presiding at further proceedings for issuance of subpoenas in the matter.

(III) The Board shall do the following:

(Rule 1200-6-3-.05, continued)

I. By a vote of two thirds (2/3) of the Board members issue the subpoena for the person(s) or items specifically found to be relevant to the inquiry, or quash or modify an existing subpoena by a majority vote; and

II. Sign the subpoena as ordered to be issued, quashed or modified.

2. Post-Notice of Charges Subpoenas - If the subpoena is sought for a contested case being heard with an Administrative Law Judge from the Secretary of State's office presiding, this definition shall not apply and all such post-notice of charges subpoenas should be obtained from the office of the Administrative Procedures Division of the Office of the Secretary of State pursuant to the Uniform Administrative Procedures Act and rules promulgated pursuant thereto.

(d) Subpoena Forms

1. All subpoenas shall be issued on forms approved by the Board.

2. The subpoena forms may be obtained by contacting the Board's Administrative Office.

(e) Subpoena Service - Any method of service of subpoenas authorized by the Tennessee Rules of Civil Procedure or the rules of procedure for contested cases of the Tennessee Department of State, Administrative Procedures Division may be utilized to serve subpoenas pursuant to this rule.

Authority: *T.C.A. §§4-5-202, 4-5-204, 4-5-217, 4-5-223, 4-5-311, 63-1-122, 63-1-144, 68-29-104, 68-29-105, 68-29-109, 68-29-126, 68-29-128, 68-29-129, 68-29-130, 68-29-131, 68-29-132, 68-29-136, and 68-29-405.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Amendment filed December 14, 1981; effective January 28, 1982. Amendment filed September 30, 1987; effective November 14, 1987. Repeal filed May 3, 1995; effective July 17, 1995. New rule filed January 7, 1997; effective March 23, 1997. Amendment filed December 1, 2000; effective February 14, 2001. Amendment filed March 22, 2001; effective June 5, 2001. Repeal and new rule filed June 18, 2002; effective September 1, 2002. Amendment filed July 8, 2004; effective September 21, 2004.*

1200-6-3-.06 MINIMUM STANDARDS. Each laboratory shall comply with the standards as set forth in 42 C. F. R. Part 493 of the current CLIA Regulations. These standards are deemed to be the minimum standard acceptable to the Board. Failure to meet the CLIA standards may result in disciplinary action as defined in Rule 1200-6-3-.05.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-104, 68-29-105, and 68-29-126.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Repeal filed May 3, 1995; effective July 17, 1995. New rule filed January 7, 1997; effective March 23, 1997. Repeal and new rule filed June 18, 2002; effective September 1, 2002.*

1200-6-3-.07 PARTICIPATION IN PROFICIENCY TESTING.

(1) Condition: Enrollment and Testing of Samples - Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in 42 CFR Part 493, Subpart I of the current CLIA Regulations and is approved by HHS. The laboratory must enroll in an approved program for each of the specialties and subspecialties for which it seeks licensure. The laboratory must test the samples in the same manner as patients specimens.

(a) Standard Enrollment.

(Rule 1200-6-3-.07, continued)

1. The laboratory must ensure that the Board is notified yearly of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this rule.

2. The laboratory must designate the program(s) to be used for each specialty, subspecialty, and analyte or task to determine compliance with the rule if the Laboratory participates in more than one (1) proficiency testing program approved by CMS.

3. For those tests performed by the laboratory for which proficiency testing is not required by 42 CFR Part 493, Subpart H of the CLIA regulations, a laboratory must establish and maintain the accuracy and reliability of its testing procedures, in accordance with Rule 1200-6-3-.10 (5).

4. For each specialty, subspecialty and analyte or test, the laboratory must participate in one (1) approved proficiency testing program or programs, for one (1) year before designating a different program and must notify the Board before any change in designation.

5. The laboratory must authorize the proficiency testing program to release to the Board all data that may be required to determine the laboratory's compliance with this rule.

(b) Standard: Testing of proficiency testing samples. The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens.

1. The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.

2. The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

3. The laboratory must test samples the same number of times that it routinely test patient samples.

4. Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent.

5. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

6. The laboratory must not send proficiency testing samples or portions of samples to another laboratory for any analysis which they are certified to perform in their own laboratory.

7. Any laboratory that the Board determines intentionally referred its proficiency testing samples to another laboratory for analysis and submits the other laboratory's results as their own shall have its license disciplined, pursuant to Rule 1200-6-3-.05.

(Rule 1200-6-3-.07, continued)

8. Any laboratory that receives proficiency testing samples from another laboratory for testing must notify the Board of the receipt of those samples.

9. The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples.

10. The laboratory must maintain copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the proficiency testing program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two (2) years from the date of the proficiency testing event.

11. Unless otherwise specified in the Rules, proficiency testing is required for only the test system, assay, or examination used as the primary method for patient testing during the proficiency testing event.

(2) Condition: Successful Participation:

(a) Each laboratory performing tests must successfully participate in a proficiency testing program approved by CMS, if applicable, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.

(b) If the laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test sanctions will be taken as defined in Rule 1200-6-3-.05.

(3) Condition: Reinstatement of Laboratories after Failure to Participate Successfully.

(a) If a laboratory's license is suspended or placed on probation by the Board or limited pursuant to CLIA regulations because it fails to participate successfully in proficiency testing for one (1) or more specialties, subspecialties, analyte, or voluntarily surrenders its license for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two (2) consecutive proficiency testing events, before the Board will consider it for reinstatement in that specialty, subspecialty, analyte or test.

(b) The period of suspension of licensure for the failed specialty, subspecialty, or analyte or test is for a period of not less than six (6) months from the date of suspension.

(c) If a laboratory's license is suspended, the laboratory must take corrective action and petition the Board for the suspension to be lifted and apply for the license to be reinstated and pay any necessary fees as set out in 1200-6-3-.02.

(4) Condition: Specialties and Subspecialties.

(a) Failure to attain an overall testing event score of at least eighty per cent (80%) is unsatisfactory performance for Bacteriology, Mycobacteriology, Mycology, Parasitiology, Virology, Syphilis Serology, General Immunology, Routine Chemistry, Endocrinology, Toxicology, Hematology, Antibody Detection, and Anti-Body Identification.

(b) Failure to attain a score of at least eighty per cent (80%) of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event of General Immunology, Routine Chemistry, Endocrinology, Toxicology, and Hematology.

(Rule 1200-6-3-.07, continued)

(c) Failure to attain an overall testing event score of at least one hundred per cent (100%) is unsatisfactory performance for ABO grouping, Rh typing, and Compatibility testing.

(d) Failure to participate in a testing event is unsatisfactory performance and results in a score of zero (0) for the testing event.

(e) Consideration may be given to those laboratories failing to participate in a testing event only if the following requirements are met:

1. Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; and

2. The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

3. The laboratory had successfully participated in the previous two (2) proficiency testing events.

(f) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of zero (0) for the testing event.

(g) For any unsatisfactory analyte or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(h) For any unsatisfactory analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two (2) years from the date of participation in the proficiency testing event.

(i) Failure to achieve satisfactory performance for the same analyte or test in two (2) consecutive testing events or two (2) out of three (3) consecutive testing events is unsuccessful performance.

(j) Failure to achieve an overall testing event score of satisfactory performance for two (2) consecutive testing events or two (2) out of three (3) consecutive testing events is unsuccessful performance.

(k) All unsuccessful testing events shall be reported to the Department within thirty (30) days of receipt of the hard copy print-out that documents results for unsuccessful proficiency testing.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-104, and 68-29-105.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Amendment filed December 14, 1981; effective January 28, 1982. Amendment filed September 30, 1987; effective November 14, 1987. Repeal filed May 3, 1995; effective July 17, 1995. New rule filed January 7, 1997; effective March 23, 1997. Repeal and new rule filed June 18, 2002; effective September 1, 2002. Amendment filed August 25, 2003; effective November 8, 2003.*

1200-6-3-.08 PATIENT TEST MANAGEMENT.

(1) Condition: Each laboratory must employ and maintain a system that provides for proper patient preparation; proper specimen collection, identification, preservation, transportation, and processing; and accurate result reporting. This system must assure optimum patient specimen integrity and

positive identification throughout the testing process and must meet the standards of this rule as they apply to the testing performed.

(a) Standard: Procedures for specimen submission and handling:

1. The laboratory must have available and must follow written policies and procedures for each of the following, if applicable: methods used for the preparation of patients; specimen collection; specimen labeling; specimen preservation; and conditions for specimen transportation and specimen processing.

2. Such policies and procedures must assure positive identification and optimum integrity of patient specimens from the time the specimens are collected until testing has been completed and the results reported.

3. If the laboratory accepts referral specimens, written instructions must be available to clients and must include, as appropriate, the information specified in paragraph (a) 1. of this section.

4. Oral explanation of instructions to patients for specimen collections, including patient preparation, may be used as a supplement to written instructions where applicable.

(b) Standard: Test Requisition.

1. The laboratory must perform tests only at the written or electronic request of an authorized person. The laboratory must maintain the written authorization or documentation of efforts made to obtain a written authorization.

2. Records of test requisitions or test authorizations must be retained for a minimum of two (2) years. The patient's chart or medical record, if used as the test requisition, must be retained for a minimum of two (2) years and must be available to the laboratory at the time of testing and available to the Board upon request.

3. The laboratory must assure that the requisition or test authorization includes all of the following:

(i) The patient's name or other unique identifier.

(ii) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for utilizing the test results or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminent life threatening laboratory results or panic values;

(iii) The test(s) to be performed;

(iv) The date of specimen collection;

(v) For PAP smears, the patient's last menstrual period, age or date of birth, and indication of whether the patient had a previous abnormal report, treatment or biopsy, and

(vi) Any additional information relevant and necessary to a specific test to assure accurate and timely testing and reporting of results.

(Rule 1200-6-3-.08, continued)

(c) Standard: Test Records:

1. The laboratory must maintain a record system to ensure reliable identification of patient specimens as they are processed and tested to assure that accurate test results are reported. These records must identify the personnel performing the testing procedure.

2. Records of patient testing, including, if applicable, instrument printouts or electronic data storage, must be retained for at least two (2) years. Immunohematology and transfusion records must be retained for no less than five (5) years.

3. The record system must provide documentation of information specified in Rule 1200-6-3-.08(1)(b)3. (i) through (vi) and include all of the following:

(i) The patient identification number, accession number, or other unique identification of the specimen;

(ii) The date and time of specimen receipt into the laboratory;

(iii) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability and

(iv) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s), which are necessary to assure proper identification and accurate reporting of patient test results.

(d) Standard: Test report.

1. The results of a laboratory test shall be reported promptly to the authorized person, the individual responsible for using the test results, the laboratory initially requesting the test, or other person required by statute or rule to receive test results.

2. The original report or an exact duplicate of each test report, including final and preliminary reports, must be retained by the testing laboratory for a period of at least two (2) years after the date of reporting. This information may be maintained as part of the patient's chart or medical record which must be readily available to the laboratory and to the Board upon request.

(i) Immunohematology reports must be retained by the laboratory for a period of no less than five (5) years.

(ii) Pathology test reports must be retained for a period of at least ten (10) years after the date of reporting.

3. The laboratory must have adequate systems in place to report results in a timely, accurate, reliable and confidential manner, and ensure patient confidentiality throughout those parts of the total process that are under the laboratory's control.

4. Laboratories must comply with Rule 1200-14-1-.41, Reports of Sexually Transmitted Diseases, which states, in part, that the following diseases are declared to be sexually transmitted diseases and, upon their diagnosis or treatment, are subject to reporting requirements as designated in T.C.A. § 68-10-101.

(i) Acquired Immune Deficiency Syndrome (AIDS) I

(Rule 1200-6-3-.08, continued)

(ii) Gonorrhea I

(iii) Syphilis (by stage) I

(iv) Chlamydia trachomatis

(v) Nongonococcal Urethritis/NGU (Number of Cases)

(vi) Human Immunodeficiency Virus - all types

Confidential (opaque envelope) report required. All information and reports concerning persons infected with sexually transmitted diseases shall be confidential and shall be inaccessible to the public.

5. The test report must indicate the name and address of the laboratory location at which the test was performed, the test performed, the name of the medical laboratory director, the test result and, if applicable, the units of measurement.

6. The laboratory must indicate on the test report any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

7. Pertinent "reference, or "normal" ranges, as determined by the laboratory performing the tests must be available to the authorized person who ordered the tests or the individual responsible for utilizing the test results.

8. The results or transcripts of laboratory tests or examinations must be released only to authorized persons or the individual responsible for utilizing the test results.

9. The laboratory must develop and follow written procedures for reporting imminent life-threatening laboratory results or "critical values." In addition, the laboratory must immediately alert the individual, entity requesting the test or the individual responsible for utilizing the test results.

10. The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, in accordance with part (1) (d) (6), as applicable, the performance specifications of each method used to test patient specimens. In addition, information that may affect the interpretation of test results, such as test interference must be provided upon request.

11. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

12. The original report or exact duplicates of test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.

(e) Standard: Referral of specimens - A laboratory must refer specimens for testing only to an in state laboratory possessing a current Tennessee license and current CLIA certification, or an out of state laboratory having a CLIA certification authorizing the performance of testing in the specialty or subspecialty of service for the level of complexity in which the referred test is categorized. The laboratory shall maintain a copy of the current CLIA certification for the referral or reference laboratory.

1. The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory.

2. The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report.

3. The authorized person who orders a test or procedure must be notified by the referring laboratory of the name and address of each laboratory location at which a test was performed.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-105, 68-29-107, 68-29-121, and 68-29-124.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Repeal filed May 3, 1995; effective July 17, 1995. New rule filed January 7, 1997; effective March 23, 1997. Repeal and new rule filed June 18, 2002; effective September 1, 2002.*

1200-6-3-.09 QUALITY CONTROL.

(1) Condition: General Quality Control - The laboratory must establish and follow written quality control procedures, including but not limited to electronic quality control and internal quality control, for monitoring and evaluating the quality of the analytical testing process of each method. General quality control shall assure the accuracy and reliability of patient test results and reports. The medical laboratory director shall review all general quality control or may designate, in writing, the review to personnel meeting the qualification of those respective positions. The medical laboratory director shall retain the ultimate responsibility for the general quality control of the operation of the laboratory. In addition, the laboratory must meet the applicable standards in paragraphs 1200-6-3-.09(2) through 1200-6-3-.09(11) of this rule.

(2) Standard: Laboratory Testing: For each test performed, the laboratory will be in compliance if it

(a) Meets all applicable quality control requirements specified in this rule; or

(b) Follows manufacturer's instructions when using their products (instruments, kits, or test systems). In addition, the laboratory must comply with requirements within any paragraph of this rule that are unique to the laboratory facility and cannot be met by manufacturer's instructions.

(3) Standard: Test Methods, Equipment, Instrumentation, Reagents, Materials, and Supplies. The laboratory must utilize test methods, equipment instrumentation, reagents, materials, and supplies that provide accurate and reliable test results and test reports.

(a) Test methodologies and equipment must be selected and testing performed in a manner that provides test results within the laboratory's stated performance specifications for each test method as determined under Rule 1200-6-3-.08 (1) (d) 6.

1. The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing performed and for the maintenance of quality during all phases of testing.

2. The accuracy of analytical balance weights must be verified annually against appropriate standard sources.

3. The accuracy of thermometers must be verified annually against appropriate standard sources or following the manufacturer's instructions.

(Rule 1200-6-3-.09, continued)

4. The accuracy of pipettes must be verified annually against appropriate standard sources or following the manufacturer's instructions.

5. The accuracy of centrifuge(s) must be verified annually against appropriate standard sources or following manufacturer's instructions.

6. The accuracy of timers must be verified annually against, appropriate standard sources or following manufacturer's instructions.

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, for accurate and reliable test system operation, and for test result reporting.

1. These conditions include, if applicable, the following:

(i) Water quality;

(ii) Temperature;

(iii) Humidity; and

(iv) Protection of equipment and instrumentation from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

2. Remedial actions taken to correct conditions that fail to meet the criteria specified in this subparagraph must be documented.

(c) Reagents, solutions, culture media, control materials, calibration materials and other supplies, as appropriate, must be labeled to indicate the following:

1. Identity and, when significant, titer, strength or concentration;

2. Recommend storage requirements;

3. Preparation and expiration date;

4. The date of receipt and date opened; and

5. Other pertinent information required for proper use.

(d) Reagents, solutions, culture media, control materials, calibration materials and other supplies must be prepared, stored, and handled in a manner to ensure the following:

1. Reagents, solutions, culture media, controls, calibration materials and other supplies are not used when they have exceeded their expiration date or when they have deteriorated or are of substandard quality. The laboratory must comply with the FDA product dating requirements of 21 CFR 610.53 for blood products and other biologicals, and with the labeling requirement of 21 CFR 809.10 for all other in-vitro diagnostics. Any exception to the product dating requirements in 21 CFR 610.53, will be granted by the FDA in the form of an amendment of the product license, in accordance with 21 CFR 610.53(d). All exceptions must be documented by the laboratory; and

2. Components of reagent kits of different lot numbers are not interchanged unless otherwise specified by the manufacturer.

(Rule 1200-6-3-.09, continued)

(4) Standard: Procedure Manual.

(a) A written procedure manual for the performance of all analytical methods used by the laboratory must be readily available and followed by laboratory personnel. Textbooks may be used as supplements to these written descriptions but may not be used in lieu of the laboratory's written procedures for testing or examining specimens. Procedure should be substantially in compliance with the NCCLS, GP-2A, current version, or any subsequent version.

(b) The procedure manual must include, when applicable to the test procedure, all of the following:

1. Requirements for specimen collection and processing, and criteria for specimen rejection;

2. Procedures for microscopic examination, including the detection of inadequately prepared slides;

3. Step-by-step performance of the procedure, including test calculations and interpretation of results;

4. Preparation of slides, solutions, calibrators, controls, reagents, stains and other materials using in testing;

5. Calibration and calibration verification procedures;

6. The reportable range for patient test results as established or verified in Rule 1200-6-3-.09(5);

7. Control procedures;

8. Remedial action to be taken when calibration or control results fail to meet the laboratory's criteria for acceptability;

9. Limitations in methodologies, including interfering substances;

10. Reference range (normal values);

11. Imminent life-threatening laboratory results or "critical values";

12. Current pertinent literature references;

13. Appropriate criteria for specimen storage and preservation to ensure specimen integrity until testing is completed;

14. The laboratory's system for reporting patient results including when appropriate, the protocol for reporting critical values;

15. Description of the course of action to be taken in the event that a test system becomes inoperable; and

16. Criteria for the referral of specimens including procedures for specimen submission and handling as described in Rule 1200-6-3-.07(1)(a).

(Rule 1200-6-3-.09, continued)

(c) Manufacturers' package inserts or operator manuals may be used, when applicable, to meet the requirements of parts (b)1. through (b) 13. of this paragraph. Information not provided by the manufacturer must be provided by the laboratory.

(d) Procedures must be re-approved, signed and dated by the medical laboratory director or designee.

(e) Procedures must be re-approved, signed and dated if the directorship of the laboratory changes.

(f) Each change in a procedure must be approved, signed, and dated by the current medical laboratory director or his or her designee approved, in writing, by the medical laboratory director.

(g) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance. These records must be retained for two (2) years after a procedure has been discontinued.

(5) Standard: Establishment and Verification of Method Performance Specifications. Prior to reporting patient test results, the laboratory must verify or establish, for each method, the performance specifications for the following performance characteristics: accuracy; precision; analytical sensitivity and specificity, if applicable; the reportable range of patient test results; the reference range(s) (normal values); and any other applicable performance characteristic.

(a) The provisions of this section are not retroactive.

(b) A laboratory that introduces a new procedure for patient testing must, prior to reporting patient test results:

1. Verify or establish for each method the performance specifications for the following performance characteristics, as applicable:

(i) Accuracy;

(ii) Precision;

(iii) Analytical sensitivity;

(iv) Analytical specificity to include interfering substances;

(v) Reportable range of patient test results;

(vi) Reference range(s); and

(vii) Any other performance characteristic required for test performance.

2. Establish calibration and control procedures for patient testing as required under Rules 1200-6-3-.09(7) and 1200-6-3-.09(8), based upon the performance specifications verified or established in accordance with Rule 1200-6-3-.09(5).

(c) The laboratory must have documentation of the verification or establishment of all applicable test performance specifications.

(6) Standard: Equipment Maintenance and Function Checks - The laboratory must perform equipment maintenance and function checks to assure accurate and reliable test results and reports. This includes

electronic, mechanical and operational checks of equipment, instruments, and test systems necessary for proper test performance and test result reporting.

(a) Maintenance of equipment, instruments, and test systems - For equipment, instruments or test systems the laboratory must:

1. Establish a maintenance protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and test result reporting;

2. Perform maintenance with at least the frequency specified in the above-mentioned maintenance protocol; and

3. Document all maintenance performed.

(b) Function checks of equipment, instruments, and test systems - For equipment, instruments, or test systems the laboratory must:

1. Define a function check protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and test result reporting;

2. Perform function checks including background or baseline checks as specified in the above-mentioned function check protocol. Function checks must be within the laboratory's established limits before patient testing is conducted; and

3. Document all function checks performed.

(7) Standard: Calibration and Calibration Verification Procedures - Calibration and calibration verification procedures are required to substantiate the continued accuracy of the test method throughout the laboratory's reportable range for patient test results. Calibration is the process of testing and adjusting an instrument kit, or test system to provide a known relationship between the measurement response and the value of the substance that is being measured by the test procedure. Calibration verification is the assaying of calibration materials in the same manner as patient samples to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory's reportable range for patient test results. The reportable range for patient test results is the range of test result values over which the laboratory can establish or verify the accuracy of instrument, kit or test system measurement response. Calibration and calibration verification must be performed and documented as required in this rule unless otherwise specified in paragraphs 1200-6-3-.09(12) through 1200-6-3-.09(34). For each method the laboratory must:

(a) Perform calibration procedures

1. At a minimum, in accordance with manufacturer's instructions, if provided, using calibration materials provided or specified, as appropriate, and with at least the frequency recommended by the manufacturer;

2. In accordance with criteria established by the laboratory.

(i) Including the number, type and concentration of calibration materials, acceptable limits for calibration, and the frequency of calibration if manufacturer's instructions are not provided; and

(ii) Using calibration materials appropriate for the methodology and, if possible, traceable to a reference method or reference material of known value; and

(Rule 1200-6-3-.09, continued)

3. Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification; and

(b) Perform calibration verification procedures

1. In accordance with the manufacturer's calibration verification instructions when they meet or exceed the requirements specified by the laboratory as described in Rule 1200-6-3-.09(7)(b)2., or

2. In accordance with criteria established by the laboratory

(i) Including the number, type, and concentration of calibration materials, acceptable limits for calibration verification and frequency of calibration verification; and

(ii) Using calibration materials appropriate for

(I) The methodology and, if possible, traceable to a reference method or reference material of known value; and

(II) Verifying the laboratory's established reportable range of patient test results, which must include at least a minimal (or zero[0]) value, a mid-point value, and a maximum value at the upper limit of that range; and

(iii) At least once every six (6) months and whenever any of the following occur:

(I) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not effect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes.

Note: If reagents are obtained from a manufacturer and all of the reagents for a test are packaged together, the laboratory is not required to perform calibration verification for each package of reagents, provided the packages of reagents are received in the same shipment and contain the same lot number;

(II) There is major preventive maintenance or replacement of critical parts that may influence test performance;

(III) Controls reflect an unusual trend or shift or are outside of the laboratory's acceptable limits and other means of assessing and correcting unacceptable control values have failed to identify and correct the problem; or

(IV) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification than specified in Rule 1200-6-3-.09(7)(b)2.(i), (ii), or (iii) and

(c) Document all calibration verification procedures performed.

(8) Standard: Control Procedures - Control procedures are performed on a routine basis to monitor the stability of the method or test system; control materials provide a means to indirectly assess the accuracy and precision of patient test results. Control procedures must be performed as defined in this paragraph unless otherwise specified in paragraphs 1200-6-3-.08(12) through 1200-6-3-.08(34).

(Rule 1200-6-3-.09, continued)

(a) Control samples must be tested in the same manner as patient specimens.

1. For qualitative tests, the laboratory must include a positive and negative control with each run of patient specimens.

2. For quantitative tests, the laboratory must include at least two (2) samples of different concentrations of either calibration materials, control materials, or a combination thereof with the frequency determined in subparagraph 1200-6-3-.09(3)(a), but not less frequently than once each run of patient specimens.

3. For electrophoretic determinations

(i) At least one (1) control sample must be used in each electrophorectic cell; and

(ii) The control sample must contain fractions representative of those routinely reported in patient specimens.

4. Each day of use, the laboratory must evaluate the detection phase of direct antigen systems using an appropriate positive and negative control material (organism or antigen extract). When direct antigen systems include an extraction phase, the system must be checked each day of use using a positive organism.

5. If calibration materials and control materials are not available, the laboratory must have an alternative mechanism to assure the validity of patient test results.

(b) Control samples must be tested in the same manner as patient specimens.

(c) When calibration or control materials are used, statistical parameters (e.g. mean and standard deviation) for each lot number of calibration material and each lot of control material must be determined through repetitive testing.

1. The stated values of an assayed control material may be used as the target values provided the stated values correspond to the methodology and instrumentation employed by the laboratory and are verified by the laboratory.

2. Statistical parameters for unassayed materials must be established over time by the laboratory through concurrent testing with calibration materials or control materials having previously determined statistical parameters.

(d) Control results must meet the laboratory's criteria for acceptability prior to reporting patient test results.

(e) Reagent and supply checks.

1. The laboratory must check each lot or shipment of reagents, discs, stains, antisera and identification systems (systems using two (2) or more substrates) when prepared or opened for positive and negative reactivity, as well as graded reactivity if applicable.

2. Each day of use (unless otherwise specified in this rule), the laboratory must test staining materials for intended reactively to ensure predictable staining characteristics.

3. The laboratory must check fluorescent stains for positive and negative reactivity each time of use (unless otherwise specified in this rule).

(Rule 1200-6-3-.09, continued)

4. The laboratory must check each batch or shipment of media for sterility, if it is intended to be sterile and if sterility is required for testing. Media must also be checked for its ability to support growth, and as appropriate, selectivity/inhibition and/or biochemical response. The laboratory may use manufacturer's control checks of media provided the manufacturer's product insert specifies that the manufacturer's quality control checks meet the current National Committee for Clinical Laboratory Standards (NCCLS) for media quality control. The Laboratory must document that the physical characteristics of the media are not compromised and report any deterioration in the media to the manufacturer. The laboratory must follow the manufacturer's specifications for using the media and be responsible for the test results.

5. A batch of media (solid, semi-solid, or liquid) consists of all tubes, plates, or containers of the same medium prepared at the same time and in the same laboratory, or, if received from an outside source of commercial supplier, consists of all of the plates, tubes or containers of the same medium that have the same lot numbers and are received in a single shipment.

(f) For each method that is developed in-house, that is a modification of the manufacturer's test procedure, the laboratory must evaluate instrument and reagent stability and operator variance in determining the number, type, and frequency of testing calibration or control materials and establish criteria for acceptability used to monitor test performance during a run of patient specimen(s). A run is an interval within which the accuracy and precision of a testing system is expected to be stable, but cannot be greater than twenty-four (24) hours or less than the frequency recommended by the manufacturer. For each procedure, the laboratory must monitor test performance using calibration materials or a combination thereof.

(9) Standard: Remedial Actions - Remedial action policies and procedures must be established by the laboratory and applied as necessary to maintain the laboratory's operation for testing patient specimens in a manner that assures accurate and reliable patient test results and reports. The laboratory must document all remedial actions taken when any of the following occur:

(a) The laboratory shall take any remedial action to correct a noted error in specimen collection or loss of specimen.

(b) Test systems that do not meet the laboratory's established performance specifications, as determined in Rule 1200-6-3-.09(5) include but are not limited to the following:

1. Equipment or methodologies that perform outside of established operating parameters or performance specifications;

2. Patient test values that are outside of the laboratory's reportable range of patient test results; and

3. The determination that the laboratory's reference range for a test procedure is inappropriate for the laboratory's patient population.

(c) Results of control and calibration materials that fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run or since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the remedial action necessary to ensure the reporting of accurate and reliable patient test results;

(Rule 1200-6-3-.09, continued)

(d) If the laboratory cannot report patient test results within its established time frames the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual of the delayed testing; and

(e) Errors in the reported patient test results are detected. The laboratory must

1. Promptly notify the authorized person ordering or individual utilizing the test results of reporting errors;

2. Issue corrected reports promptly to the authorized person ordering the test or the individual utilizing the test results; and

3. Maintain exact duplicates of the original report as well as the corrected report for two (2) years.

(f) There must be a procedure of review in operation to verify highly unusual results such as delta values and critical values. This review must be performed and documented by the supervisor or other person designated in writing on a daily basis to identify possibly erroneous tests.

(10) Standard: Quality Control Records - The laboratory must document and maintain records of all quality control activities specified in paragraphs 1200-6-3-.09(2) through 1200-6-3-.09(34) and retain records for at least two (2) years. Immunohematology quality control records must be maintained for a period of no less than five (5) years. In addition, quality control records for blood and blood products must be maintained for a period not less than five (5) years. In addition, quality control records for blood and blood products must be maintained for a period not less than five (5) years after processing records have been completed, or six (6) months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 6060.160(d).

(11) Condition: Quality Control - Specialties and Subspecialties - The laboratory must establish and follow written policies and procedures for an acceptable quality control program that include verification and assessment of accuracy, measurement of precision and detection of error for all analyses and procedures performed by the laboratory. In addition to the general requirements specified in paragraphs 1200-6-3-.09(1) through 1200-6-3-.09(11), the laboratory must meet the applicable requirements of paragraphs 1200-6-3-.09(12) through 1200-6-3-.09(34) or an CMS approved equivalent procedure and the following:

(a) Meets quality control requirements specified in this paragraph; or

(b) Follows manufacturer's instructions when using products (instruments, kits, or test systems) as well as specialty and subspecialty quality control.

(c) Failure to meet any of the applicable conditions in paragraph 1200-6-3-.09(12) through 1200-6-3-.09(34) may result in revocation of licensure for the entire specialty or subspecialty to which the condition applies, in accordance with Rule 12-6-3-.05.

(12) Condition: Microbiology - The laboratory must meet the applicable quality control requirements in paragraphs 1200-6-3-.09(1) through 1200-6-3-.09(11) and in paragraphs 1200-6-3-.09(13) through 1200-6-3-.09(17) for the subspecialties for which it is certified under the specialty of microbiology.

(13) Condition: Bacteriology - To meet the quality control requirements for bacteriology in paragraphs 1200-6-3-.09(1) through 1200-6-3-.09(11) and in paragraphs 1200-6-3-.09(13) through 1200-6-3-.09(17) for the subspecialties for which it is certified under the specialty of microbiology.

(Rule 1200-6-3-.09, continued)

(a) The laboratory must check positive and negative reactivity with control organisms as specified below:

1. Each day of use for catalase, coagulase, beta-lactamase, and oxidase reagents and DNA probes;

2. Each week of use for Gram and acid-fast stains, bacitracin, optochin, ONPG, X and V discs or strips; and

3. Each month of use for antisera.

(b) Each week of use, the laboratory must check XV discs or strips with a positive control organism.

(c) For antimicrobial susceptibility tests, the laboratory must check each new batch of media and each lot of antimicrobial discs before, or concurrent with, initial use, using approved reference organisms.

1. The laboratory's zone sizes or minimum inhibitory concentration for reference organisms must be within established limits before reporting patient results.

2. The laboratory must use the appropriate control organism(s) to check the procedure as required by current law under CLIA.

(14) Condition: Mycobacteriology - To meet the quality control requirements for mycobacteriology, the laboratory must comply with the applicable requirements in paragraph 1200-6-3-.09(1) through 1200-63-.09(11) and with subparagraphs (a) through (d) of this paragraph. All quality control activities must be documented.

(a) Each day of use, the laboratory must check the iron uptake test with at least one (1) acid-fast organism that produces a positive reaction and with an organism that produces a negative reaction and check all other reagents or test procedures used for mycobacteria identification with at least one (1) acid-fast organism that produces a positive reaction.

(b) The laboratory must check flurochrome acid-fast stains for positive and negative reactivity each week of use.

(c) The laboratory must check acid-fast stains each week of use with an acid-fast organism that produces a positive reaction.

(d) For susceptibility tests performed on Mycobacterium tuberculosis, the laboratory must comply with the applicable requirements in paragraphs 1200-6-3-.09(1) through 1200-6-3-.09(11) and with subparagraphs (a) through (d) of this paragraph. All quality control activities must be documented.

(15) Condition: Mycology - To meet the quality control requirements for mycology, the laboratory must comply with the applicable requirements in paragraphs 1200-6-3-.09(1) though 1200-6-3-.09(11) and with subparagraphs (a) through (d) of this paragraph. All quality control activities must be documented.

(a) Each day of use, the laboratory using the auxanographic medium for nitrate assimilation must check the nitrate reagent with a peptone control.

(Rule 1200-6-3-.09, continued)

(b) Each week of use, the laboratory must check all reagents used with biochemical tests and other test procedures for mycological identification with an organism that produces a positive reaction.

(c) Each week of patient testing, the laboratory must check acid-fast stains for positive and negative reactivity.

(d) For susceptibility tests, the laboratory must test each drug each day of use with at least one (1) control strain that is susceptible to the drug. The laboratory must establish control limits. Criteria for acceptable control results must be met prior to reporting patient results.

(16) Condition: Parasitology - To meet the quality control requirements for parasitology, the laboratory must comply with the applicable requirements of paragraphs 1200-6-3-.09(1) through 1200-6-3-.09(11) and with subparagraphs (a) through (c) of this paragraph. All quality control activities must be documented.

(a) The laboratory must have available a reference collection of slides or photographs, and, if available, gross specimens for identification of parasites and must use these references in the laboratory for appropriate comparison with diagnostic specimens.

(b) The laboratory must calibrate and use the calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter. Recalibration must be performed if the ocular micrometer is moved to another microscope or objectives are changed.

(c) Each month of use, the laboratory much check permanent stains using a fecal sample control that will demonstrate staining characteristics.

(17) Condition: Virology - To meet the quality control requirements for virology, the laboratory must comply with the applicable requirements in paragraph 1200-6-3-.09(1) through 1200-6-3-.09(11) and with subparagraphs (a) through (c) of this paragraph. All quality control activities must be documented.

(a) The laboratory must have available host systems for the isolation of viruses and test methods for the identification of viruses that cover the entire range of viruses that are etiologically related to clinical diseases for which services are offered.

(b) The laboratory must maintain records that reflect the systems used and the reactions observed.

(c) In tests for the identification of viruses, the laboratory must simultaneously culture uninoculated cells or cell substrate control as a negative control to detect erroneous identification results.

(18) Condition: Diagnostic Immunology - The laboratory must meet the applicable quality control requirements in paragraph 1200-6-3-.09(1) through 1200-6-3-.09(11) and paragraphs 1200-3-.09(19) through 1200-6-3-.09(20) for the subspecialties for which it is certified under the specialty of diagnostic immunology.

(19) Condition: Syphilis Serology - To meet the quality control requirements for syphilis serology, the laboratory must comply with the applicable requirements in paragraphs 1200-6-3-.09(1) through 1200-6-3-.09(11) and with subparagraphs (a) through (c) of this paragraph. All quality control activities must be documented.

(a) For laboratories performing syphilis testing, the equipment, glassware, reagents, controls, and techniques for tests for syphilis must conform to manufacturers' specifications.

(Rule 1200-6-3-.09, continued)

(b) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity plus a negative control.

(c) The laboratory must employ positive and negative controls that evaluate all phases of the test system to ensure reactivity and uniform dosages.

(d) The laboratory may not report test results unless the predetermined reactivity pattern of the controls is observed.

(e) All facilities manufacturing blood and blood products for transfusion or serving as referral laboratories for these facilities must meet the syphilis serology testing requirements of 21 CFR 640.5(a).

(20) Condition: General Immunology - To meet the quality control requirements for general immunology, the laboratory must comply with the applicable requirements in paragraphs 1200-6-3-.09(1) through 1200-6-3-.09(11) and with subparagraphs (a) through (d) of this paragraph. All quality control activities must be documented.

(a) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of know titer or controls of graded reactivity and uniform dosages when positive and negative controls are not sufficient.

(b) The Laboratory must employ controls that evaluate all phases of the test system (antigens, complement, erythrocyte indicator systems, etc.) to ensure reactivity and uniform dosages when positive and negative controls alone are not sufficient.

(c) The laboratory may not report test results unless the predetermined reactivity pattern of the controls is observed.

(d) All facilities manufacturing blood and blood products for transfusion or serving as referral laboratories for these facilities must meet

1. The HIV testing requirements of 21 CFR 610.45; and

2. Hepatitis testing and requirements of 21 CFR 610.40.

(21) Condition: Chemistry - The laboratory must meet the applicable quality control requirements in paragraphs 1200-6-3-.09(1) through 1200-6-3-.09(11) and paragraphs 1200-6-3-.09(22) through 1200-6-3-.09(24) for the subspecialties for which it is certified under the specialty of chemistry.

(22) Condition: Routine Chemistry - To meet the quality control requirements for routine chemistry, the laboratory must comply with the applicable requirements in paragraphs 1200-6-3-.09(1) through 1200-6-3-.09(11). All quality control activities must be documented. In addition, for blood gas analyses, the laboratory must:

(a) Calibrate or verify calibration according to the manufacturer's instructions and with at least the frequency recommended by the manufacturer;

(b) Test one (1) sample of control material for each eight (8) hours of testing or as set out in the manufacturer's instructions;

(c) Use a combination of calibrators and control materials that include both low and high values on each day of testing or as set out in the manufacturer's instruction; and

(Rule 1200-6-3-.09, continued)

(d) Include one (1) sample of calibration material or control material each time patients are tested unless automated instrumentation internally verifies calibration at least every thirty (30) minutes or as set out in the manufacturer's instruction.

(23) Condition: Endocrinology - To meet the quality control requirements for endocrinology, the laboratory must comply with the applicable requirements contained in paragraphs 1200-6-3-.09(1) through 1200-6-3-.09(11). All quality control activities must be documented.

(24) Condition: Toxicology - To meet the quality control requirements for toxicology, the laboratory must comply with the applicable requirements in paragraphs 1200-6-3-.09(1) through 1200-6-3-.09(11). However, this subsection shall not apply to drug testing for employment purposes. All quality control activities must be documented. In addition, for drug abuse screening using thin layer chromatography:

(a) Each plate must be spotted with at least one (1) sample of calibration material containing all drug groups identified by thin layer chromatography which the laboratory reports; and

(b) At least one (1) control sample must be included in each chamber, and the control sample must be processed through each step of patient testing, including extraction procedures.

(25) Condition: Hematology - To meet the quality control requirements for hematology, the laboratory must comply with the applicable requirements in paragraphs 1200-6-3-.09(1) through 1200-6-3-.09(11) and with subparagraphs (a) through (d) of this paragraph. All quality control activities must be documented.

(a) For automated hematology testing systems, excluding coagulation, the laboratory must include two (2) levels of controls for each eight (8) hours of operation.

(b) For all automated coagulation testing systems, the laboratory must include two (2) levels of control for each eight (8) hours of operation and each time a change in reagents occurs.

(c) For manual hemoglobin determinations (cyanmethemoglobin), the procedure must be standardized with reference materials of known, certified values. At least four (4) different hemoglobin concentrations must be used to prepare the calibration curve or to calibrate the readout instruments. For procedures using calibration curves, all curves must be repeated regularly and verified after serving or recalibration of instruments. Photometer functions checks must be run and recorded daily. Photometers must be checked for linearity periodically and when instrument adjustments have been made with appropriate filters or solutions.

(d) For manual hematocrit determinations, the speed and timer of the microhematocrit centrifuge must be checked at specific intervals. The constant packing time (minimum spin to reach maximum packing of cells) must be assessed on installation and reassessed when there has been a change in either the speed or time.

(26) Condition: Pathology - The laboratory must meet the applicable quality control requirements in paragraphs 1200-6-3-.09(1) through 1200-6-3-.09(11) and paragraphs 1200-6-3-.09(27) through 1200-6-3-.09(29) for the subspecialties; for which it is certified under the specialty of pathology. All quality control activities must be documented.

(27) Condition: Cytology - To meet the quality control requirements for cytology, the laboratory must comply with the applicable requirements in paragraphs 1200-6-3-.09(1) through 1200-6-3-.09(11) and subparagraphs (a) through (g) of this paragraph.

(a) The laboratory must assure that

(Rule 1200-6-3-.09, continued)

1. All gynecologic smears are stained using a Papanicolaou or modified Papanicolaou staining method;

2. Effective measures are taken to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process;

3. Nongynecologic specimens that have a high potential for cross-examination are stained separately from other nongynecologic specimens, and the stains are filtered or changed following staining;

4. Diagnostic interpretations are not reported on unsatisfactory smears; and

5. All cytology slide preparations are evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.

(b) The laboratory is responsible for ensuring the following:

1. Each individual engaged in the evaluation of cytology preparations by nonautomated microscopic technique examines no more than one hundred (100) slides (one patient per slide, gynecologic or nongynecologic, or both) in a twenty-four (24) hour period, irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and is not being employed as a performance target for each individual. Previously examined reactive, reparative, atypical, premalignant or malignant gynecologic cases as defined in part (c)1. of this paragraph, previously examined nongynecologic cytology preparations, and tissue pathology slides examined by a pathologist are not included in the one hundred (100) slide limit.

2. For purposes of workload calculations, each slide preparation (gynecologic or nongynecologic) made using automated, semi-automated, or other liquid-based slide preparatory techniques which result in cell dispersion over one-half (½) or less of the total available slide area and which is examined by nonautomated microscopic technique counts as one-half (½) slide.

3. Records are maintained of the total number of slides examined by each individual during each twenty-four (24) hour period, irrespective of the site or laboratory, and the number of hours each individual spends examining slides in the twenty-four (24) hour period; and

(i) The maximum number of one hundred (100) slides described in part (b)1. of this paragraph may not be examined in less than an eight (8) hour workday, and

(ii) For the purposes of establishing workload limits for individual examining slides by nonautomated microscopic technique on other than an eight (8) hour workday basis (includes full-time employees with duties other than slide examination and part-time employees), a period of eight (8) hours must be used to prorate the number of slides that may be examined. The following formula shall be used to determine maximum slide volume to be examined:

(iii) (Number of hours examining slides x 100) - 8

(c) A pathologist must ensure the following:

1. All gynecologic smears interpreted to be showing reactive or reparative changes, atypical squamous or glandular cells of undetermined significance, or to be in the premalignant

(dysplasia, cervical intraepithelial neoplasia or all squamous intraepithelial lesions including human papillomavirus-associated changes) or malignant category are confirmed by a pathologist qualified by certification in anatomic pathology by the American Board of Pathology. The report must be signed to reflect the review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the pathologist;

2. All nongynecologic cytologic preparation are reviewed by the pathologist. The report must be signed to reflect the pathologist's review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the pathologist;

3. The slide examination performance of each cytotechnologist is evaluated and documented, including performance evaluation through the reexamination of normal and negative cases and feedback on the reactive, reparative, a typical, malignant or premalignant cases as defined in part (c)1. of this paragraph; and

4. A maximum number of slides, not to exceed the maximum workload limit described in subparagraph (b) of this paragraph is established by the pathologist for each individual examining slide preparations by nonautomated microscopic technique.

(i) The actual workload limit must be documented for each individual and established in accordance with the individual's capability based on the performance evaluation as described in part (c) 3. of this paragraph.

(ii) Records are available to document that each individual's workload limit is reassessed at least every six (6) months and adjusted when necessary.

(d) The laboratory must establish and follow a program designed to detect errors in the performance of cytologic examinations and the reporting of results.

1. The laboratory must establish a program that includes a review of slides from at least ten per cent (10%) of the gynecologic cases interpreted to be negative for reactive, reparative, atypical premalignant or malignant conditions as defined in part (c) 1. This review must be done by a pathologist qualified by certification in anatomic pathology by the American Board of Pathology, a cytology general supervisor qualified under Rule 1200-6-1-.23 or a cytotechnologist qualified under Rule 1200-6-1-.24.

(i) The review must include negative cases selected at random from the total caseload and from patients or groups of patients that are identified as having a high probability of developing cervical cancer, based on available patient information;

(ii) Records of initial examinations and rescreening results must be available; and

(iii) The review must be completed before reporting patient results on those cases selected.

2. The laboratory must compare clinical information, when available, with cytology reports and must compare all malignant and premalignant (as defined in part (c)1. of this paragraph) gynecology reports with the histopathology report, if available in the laboratory (either on-site or in storage), and determine the causes of any discrepancies.

3. For each patient with a current high grade intraepithelial lesion (moderate dysplasia or CIN-2 or above), the laboratory must review all normal or negative gynecologic specimens received within the previous five (5) years, if available in the laboratory

(either on-site or in storage). If significant discrepancies are found that would affect patient care, the laboratory must notify the patient's physician and issue an amended report.

4. The laboratory must establish and document an annual statistical evaluation of the number of cytology cases examined, number of specimens processed by specimen type, volume of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation), number of gynecologic cases where cytology and available histology are discrepant, the number of gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as malignant or premalignant, as defined in part (c)1. of this paragraph, and the number of gynecologic cases for which history results were unavailable to compare with malignant or premalignant cytology cases as defined in part(c)1. of this paragraph.

5. The laboratory must evaluate the case reviews of each individual examining slides against the laboratory's overall statistical values, document any discrepancies, including reasons for the deviation, and document corrective action, if appropriate.

(e) The laboratory report must:

1. Clearly distinguish specimens or smears, or both, that are unsatisfactory for diagnostic interpretation; and

2. Contain narrative descriptive nomenclature for all results.

(f) Corrected reports issued by the laboratory must indicate the basis for correction.

(g) The laboratory must retain all slide preparations for five (5) years from the date of examination, or slides may be loaned to proficiency testing programs, in lieu of maintaining them for this time period, provided the laboratory receives written acknowledgement of the receipt of slides by the proficiency testing program and maintains the acknowledgement to document the loan of such slides. Documentation for slides loaned or referred for purposes other than proficiency testing must also be maintained. All slides must be retrievable upon request.

(28) Condition: Histopathology - To meet the quality control requirements for histopathology, a laboratory must comply with the applicable requirements in paragraphs 1200-06-3-.09(1) through 1200-6-3-.09(11) and subparagraphs (a) through (c) of this paragraph. All quality control activities must be documented.

(a) A control slide of known reactivity must be included with each slide or group of slides for differential, or special stains. Reaction(s) of the control slide with each special stain must be documented each day of testing.

(b) The laboratory performing the histopathology testing must retain stained slides at least ten (10) years from the date of examination and retain specimen blocks at least five (5) years from the date of examination.

(c) The laboratory must retain remnants of tissue specimens in a manner that assures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified by certification in anatomic pathology by the American Board of Pathology.

(d) All tissue pathology reports must be signed by an individual qualified as specified in subparagraph (c) of this paragraph. If a computer report is generated with an electronic

signature, it must be authorized by the individual qualified as specified in subparagraph (c) of this paragraph.

(e) The laboratory must utilize acceptable terminology of a recognized system of disease nomenclature in reporting results.

(29) Condition: Oral Pathology - To meet the quality control requirements for oral pathology, the laboratory must comply with the applicable requirements in paragraphs 1200-6-3-.09(1) through 1200-6-3-.09(11) and 1200-6-3-.09(28). All quality control activities must be documented.

(30) Condition: Radiobioassay - To meet quality control requirements for radiobioassay, the laboratory must comply with the applicable requirements of paragraphs 1200-6-3-.09(1) through 1200-6-3-.09(11). All quality control activities must be documented.

(31) Condition: Histocompatibility - In addition to meeting the applicable requirements for general quality control in paragraphs 1200-6-3-.09(1), for quality control for general immunology in paragraph 1200-6-3-.09(20) and for immunohematology in paragraph 1200-6-3-.09(33), the laboratory must comply with the applicable requirements in subparagraphs (a) through (d) of this paragraph. All quality control activities must be documented.

(a) For renal allotransplantation, the laboratory must meet the following requirements:

1. The laboratory must have available and follow criteria for the following:

(i) Selecting appropriate patient serum samples for crossmatching;

(ii) The technique used in crossmatching;

(iii) Preparation of donor lymphocytes for crossmatching; and

(iv) Reporting crossmatch results;

2. The laboratory must

(i) Have available results of final crossmatches before an organ or tissue is transplanted, and

(ii) Make a reasonable attempt and document efforts to have available serum specimens for all potential transplant recipients at initial typing, for periodic screening, for preptransplantation crossmatch and following sensitizing events, such as transfusion and transplant loss;

3. The laboratory's storage and maintenance of both recipient sera and reagents must

(i) Be at an acceptable temperature range for sera and components;

(ii) Use a temperature alarm system and have an emergency plan for alternate storage; and

(iii) Ensure that all specimens are properly identified and easily retrievable;

4. The laboratory's reagent typing sera inventory (applicable only to locally constructed trays) must indicate source, bleeding date and identification number, and volume remaining.

5. The laboratory must properly label and store all labile components utilized in histocompatibility testing.

6. The laboratory must:

   (i) HLA type all potential transplant recipients;

   (ii) Type cells from organ donors referred to the laboratory; and

   (iii) Have available and follow a policy that establishes when antigen redefinition and retyping are required;

7. The laboratory must have available and follow criteria for

   (i) The preparation of lymphocytes for HLA-A, B and DR typing;

   (ii) Selecting typing reagents, whether locally or commercially prepared;

   (iii) The assignment of HLA antigens; and

   (iv) Assuring that reagents used for typing recipients and donors are adequate to define all major and International Workshop HLA-A, B and DR specificities for which reagents are readily available;

8. The laboratory must do the following:

   (i) Screen potential transplant recipient sera for performed HLA-A and B antibodies with a suitable lymphocyte panel on sera collected

      (I) At the time of the recipient's initial HLA typing; and

      (II) Thereafter, following sensitizing events and upon request; and

   (ii) Use a suitable cell panel for screening patient sera (antibody screen), a screen that contains all the major HLA specificities and common splits

      (I) If the laboratory does not use commercial panels, it must maintain a list of individuals for fresh panel bleeding; and

      (II) If the laboratory uses frozen panels, it must have a suitable storage system,

9. The laboratory must check

   (i) Each typing tray using

      (I) Positive control sera;

      (II) Negative control sera; and

      (III) Positive controls for specific cell types when applicable (i.e., T. cells, B cells, and monocytes); and

(Rule 1200-6-3-.09, continued)

(ii) Each compatibility test (i.e. mixed lymphocyte cultures, homozygous typing cells or DNA analysis) and typing for disease-associated antigens using controls to monitor the test components and each phase of the test system to ensure an acceptable performance level;

10. Compatibility testing for cellularly-defined antigens must utilize techniques such as the mixed lymphocyte culture test, homozygous typing cells or DNA analysis;

11. If the laboratory reports the recipient's or donor's, or both, ABO blood group and D(Rho) typing, the testing must be performed in accordance with 1200-6-3-.09(33);

12. If the laboratory utilizes immunologic reagents (such as antibodies or complement) to remove contaminating cells during the isolation of lymphocytes or lymphocyte subsets, the efficiency of the methods must be verified with appropriate quality control procedures;

13. At least once each month, the laboratory must have each individual performing tests evaluate a previously tested specimen as an unknown to verify his or her ability to reproduce test results. Records of the results for each individual must be maintained; and

14. The laboratory must participate in at least one (1) national or regional cell exchange program, if available, or develop an exchange system with another laboratory in order to validate inter-laboratory reproducibility.

(b) If the laboratory performs histocompatibility testing for:

1. Transfusion and other non-renal transplantation, excluding bone marrow and living transplant, all the requirements specified in this paragraph, as applicable, except for the performance of mixed lymphocyte cultures, must be met;

2. Bone marrow transplantation, all the requirements specified in this paragraph, including the performance of mixed lymphocyte cultures or other augmented testing to evaluate class 11 compatibility, must be met; and

3. Non-renal solid organ transplantation, the results of final crossmatches must be available before transplantation when the recipient has demonstrated presensitization by prior serum screening except for emergency situations. The laboratory must document the circumstances, if known, under which emergency transplants are performed, and records must reflect any information concerning the transplant provided to the laboratory by the patient's physician.

(c) Laboratories performing HLA typing for disease-associated studies must meet all the requirements specified in this paragraph except for the performance of mixed lymphocyte cultures, antibody screening and crossmatching.

(d) For laboratories performing organ donor HIV testing the requirements of paragraph 1200-6-3-.09(20) for the transfusion of blood and blood products must be met.

(32) Condition: Clinical Cytogenetics - To meet the quality control requirements for clinical cytogenetics, the laboratory must comply with the applicable requirement of paragraphs 1200-6-3-.09(1) through 1200-6-3-.09(11) and with subparagraphs (a) through (d) of this paragraph. All quality control activities must be documented.

(Rule 1200-6-3-.09, continued)

(a) When determination of sex is performed by X and Y chromatin counts, these counts must be based on an examination of an adequate number of cells. Confirmatory testing such as full chromosome analysis must be performed for all atypical results.

(b) The laboratory must have records that reflect the media used and document the reactions observed, number of cells counted, the number of cells karyotyped, the number of chromosomes counted for each metaphase spread, and the quality of the banding that the resolution is sufficient to support the reported results; and that an adequate number of karyotypes are prepared for each patient.

(c) The laboratory also must have policies and procedures for assuring an accurate and reliable patient sample identification during the process of accessioning, cell preparation, photographing or other image reproduction technique, and photographic printing, and storage and reporting of results or photographs.

(d) The laboratory report must include the summary and interpretation of the observations and number of cells counted and analyzed and the use of recognized nomenclature, such as the International System of Cytogenetic Nomenclature.

(e) Adequate slides, films, hard copies of karyotypes and reports shall be retained for twenty (20) years.

(33) Condition: Immunohematology - To meet the quality control requirements for immunohematology, the laboratory must comply with the applicable requirements in paragraphs 1200-6-3-.09(1) through 1200-6-3-.09(II) and with subparagraphs (a) through (d) of this paragraph. All quality control activities must be documented.

(a) The laboratory must perform ABO group and D(Rho) typing, unexpected antibody detection, antibody identification and compatibility testing in accordance with manufacturer's instruction, if provided, and as applicable, with 21 CFR 606 (with the exception of 21 CFR 606.20a, Personnel) and 21 CFR 640, et. seq.

(b) The laboratory must perform ABO group by concurrently testing unknown red cells with anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A, and B red cells.

(c) The laboratory must determine the D(Rho) type by testing unknown red cells with anti-D(anti-Rho) blood grouping reagent.

(d) If required in the manufacturer's package insert for anti-D reagents, the laboratory must employ a control system capable of detecting false positive D(Rho) test results.

(34) Condition: Transfusion services and bloodbanking - If a facility provides services for the transfusion of blood and blood products, the facility must be under the adequate control and technical supervision of a pathologist or other doctor of medicine or osteopathy meeting the qualifications in Rule 1200-6-1-.20, technical supervision in immunohematology. The facility must ensure that there are facilities for procurement, safekeeping and transfusion of blood and blood products and that blood and blood products must be available to meet the needs of the physicians responsible for the diagnosis, management, and treatment of patients. The facility meets this condition by complying with the standards in paragraphs 1200-6-3-.09(34)(a) through (f).

(a) Standard: Immunohematological collection, processing, dating periods, labeling and distribution of blood and blood products.

(Rule 1200-6-3-.09, continued)

In addition to the requirements of parts 1. through 4. of this subparagraph, the facility must also meet the applicable quality control requirements in 1200-6-3-.09(1) through 1200-6-3-.09(10).

1. Blood and blood product collection, processing and distribution must comply with 21 CFR Part 640 and 21CFR Part 606, and the testing laboratory must meet the applicable requirements of 42 CFR Part 493.

2. Dating of blood and blood products must conform to 21 CFR 610.53.

3. Labeling of blood and blood products conform to 21 CFR Part 606, Subpart G.

4. Policies to ensure positive identification of a blood or blood product recipient must be established, documented and followed.

(b) Standard: Blood and blood product storage facilities

1. The blood and blood products must be stored under appropriate conditions, which include an adequate temperature alarm system that is checked and documented daily.

(i) An audible alarm system, including a chart recorder, must monitor proper blood and blood product storage temperature continuously.

(ii) Activation, to include high and low limits, of alarm system must be documented periodically, no less frequently than quarterly.

(iii) A remote alarm system is required if location where blood or blood products are stored is not continuously staffed.

(iv) There must be a written procedure for response to an alarm when temperature limits are exceeded.

(v) There must be a written procedure for response to an alarm indicating specific personnel to respond and their appropriate action.

2. If blood is stored or maintained for transfusion purposes outside of a monitored refrigerator, the facility must ensure and document that storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.

(c) Standard: Arrangement for services - In the case of services provided outside the blood bank, the facility must have an agreement reviewed and approved by the director that governs the procurement, transfer, and availability of blood and blood products.

(d) Standard: Provision of testing - There must be provision for prompt ABO blood group, D(Rho) type, unexpected antibody detection and compatibility testing in accordance with 1200-6-3-.09(34) of this rule and the laboratory investigation of transfusion reactions, either through the facility or under arrangement with an approved facility on a continuous basis, under the supervision of a pathologist or other doctor of medicine or osteopathy meeting the qualifications of 1200-6-1-.20.

(e) Standard: Retention of samples of transfused blood and patient specimens.

1. Samples of each unit of transfused blood and the patient specimens must be retained for a minimum of seven (7) days for further testing in the event of reactions according to the facility's established procedures.

2. The facility must promptly dispose of blood not retained for further testing that has passed its expiration date.

(f) Standard: Investigation of transfusion reactions.

1. The facility, according to its established procedures, must promptly investigate all transfusion reactions occurring in all facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures.

2. The facility must document that all necessary remedial actions are taken to prevent future recurrence of transfusion reactions and that all policies and procedures are reviewed to assure that they are adequate to ensure the safety of individuals being transfused within the facility.

3. When a fatality occurs as a result of a complication of blood or blood component transfusions, the Director, Office of Compliance and Biologics Quality, Center for Biological Evaluation and Research (CBER), FDA, must be notified within twenty-four (24) hours. Within seven (7) days after the fatality, a written report of the investigation must be submitted to the Director at 1401 Rockville Pike, Suite 200 N, Rockville, MD 20852-1448. A copy of the report should be sent to the collecting facility if appropriate. See AABB Accreditations Requirements Manual.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-105, and 68-29-125.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Amendment filed December 14, 1981; effective January 28, 1982. Repeal filed May 3, 1995; effective July 17, 1995. New rule filed January 7, 1997; effective March 23, 1997. Repeal and new rule filed June 18, 2002; effective September 1, 2002.*

1200-6-3-.10 PERFORMANCE IMPROVEMENT PROGRAM.

(1) Condition: Performance improvement. Each laboratory must establish and follow written policies and procedures for a comprehensive quality assurance program which is designed to monitor and evaluate the ongoing and overall quality of the total testing process. The laboratory's performance improvement program must evaluate the effectiveness of its policies and procedures; identify and correct problems; assure the accurate, reliable and prompt reporting of test results; and assure the adequacy and competency of the staff.

(a) The laboratory must revise policies and procedures as necessary based upon the results of those evaluations.

(b) The laboratory must meet the standards of this rule as they apply to the services offered, tests performed, test results reported, and the unique practices of each testing entity. All performance improvement activities must be documented.

(2) Standard: Patient test management assessment. The laboratory must have an ongoing mechanism for monitoring and evaluating the systems required under Rule 1200-6-3-.08, Patient Test Management. The laboratory must monitor, evaluate, and revise, if necessary, based on the results of its evaluations, the following:

(a) The criteria established for patient preparation, specimen collection, labeling, preservation and transportation;

(Rule 1200-6-3-.10, continued)

(b) The information solicited and obtained on the laboratory's test requisition for its completeness, relevance, and necessity for testing of patient specimens;

(c) The use and appropriateness of the criteria established for specimen rejection;

(d) The completeness, usefulness, and accuracy of the test report information necessary for the interpretation or utilization of test results;

(e) The timely reporting of test results based on testing priorities (STAT, routine, etc.); and

(f) The accuracy and reliability of test reporting systems, appropriate storage of records and retrieval of test results.

(3) Standard: Quality control assessment. The laboratory must have an ongoing mechanism to evaluate the corrective actions taken under paragraph 1200-6-3-.09(9), Remedial Actions. Ineffective policies and procedures must be revised based on the outcome of the evaluation. The mechanism must evaluate the effectiveness of corrective actions taken for the following:

(a) Problem identified during the evaluation of calibration and control data for each test, method;

(b) Problems identified during the evaluation of patient test values for the purpose of verifying the reference range of test method; and

(c) Errors detected in reported results.

(4) Standard: Quality control assessment. Under Rule 1200-6-3-.07, Participation in Proficiency Testing, the corrective actions taken for any unsatisfactory or unsuccessful proficient testing result(s) must be evaluated for effectiveness.

(5) Standard: Comparison of test results. If a laboratory performs the same test using different methodologists or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using different methodologies, instruments, or testing sites. If a laboratory performs tests that are not included under 42 CFR §493.901 of CLIA, Proficiency Testing Programs, the laboratory must have a system for verifying the accuracy and reliability of its test results are least twice a year.

(6) Standard: Relationship of patient information to patients test results. The laboratory must have a mechanism to identify and evaluate patient test results that appear inconsistent with relevant criteria such as:

(a) Patient age;

(b) Sex;

(c) Diagnosis or pertinent clinical data, when provided;

(d) Distribution of patient test results when available; and

(e) Relationship with other test parameters, when available within the laboratory.

(7) Standard: Personnel assessment. The laboratory must have an ongoing mechanism to evaluate the competency of all laboratory personnel

(8) Standard: Communications.

(Rule 1200-6-3-.10, continued)

(a) The laboratory must have a system in place to document problems that occur as a result of breakdowns in communication between the laboratory and the authorized individual who orders or receives the results of test procedures or examinations.

(b) Corrective actions taken to resolve the problems and to minimize communications breakdowns must be documented.

(9) Standard: Complaint investigations. The laboratory must have a system in place to assure that all complaints and problems reported to the laboratory are documented. Investigations of complaints must be made, when appropriate, and, as necessary, corrective actions must be instituted.

(10) Standard: Performance improvement review with staff. The laboratory must have a mechanism for documenting and assisting problems identified during performance improvement reviews and discussing them with the staff. The laboratory must take corrective actions that are necessary to prevent recurrence.

(11) Standard: Performance improvement records. The laboratory must maintain documentation of all performance improvement activities including problems identified and corrective actions taken. All performance improvement records must be maintained for period of two (2) years and available to the Board or its designee upon request.

Authority: *T.C.A. §§4-5-202, 4-5-204, and 68-29-105.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Repeal filed May 3, 1995; effective July 17, 1995. New rule filed January 7, 1997; effective March 23, 1997. Repeal and new rule filed June 18, 2002; effective September 1, 2002.*

1200-6-3-.11 FACILITIES, SAFETY, INFECTIOUS AND HAZARDOUS WASTE DISPOSAL.

(1) Condition: The laboratory must have facilities, space and environmental conditions necessary for conducting the services offered, must provide a reasonably safe, working environment, and must properly dispose of infectious and hazardous wastes.

(a) Standard: Facilities. The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, utilities necessary for conducting all phases of testing, including the testing process, as appropriate.

(b) Standard: Safety. Safety precautions must be established, posted, and observed to ensure protection from physical hazards and biohazards materials. Adequate fire precautions shall be observed; volatile chemicals and flammable reagents must be properly stored.

(c) Infectious and Hazardous Waste Disposal. Each facility must develop, maintain, and implement written policies and procedures for the definition and handling of its infectious and hazardous wastes which must comply with the requirements of the Occupational Safety and Health Act, 29 U.S.C.A. §§ 65 1, et seq.

(d) The following waste shall be considered to be infectious waste:

1. Waste contaminated by patients who are isolated due to communicable disease, as provided in the U.S. Centers for Disease Control “Guidelines for Isolation Precautions in Hospitals”;

2. Cultures and stocks of infectious agents including specimen cultures collected from medical and pathological laboratories, cultures and stocks of infectious agents form research and industrial laboratories, wastes from the production of biologicals, discarded

live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures;

3. Waste human blood and blood products such as serum, plasma, and other blood components;

4. Pathological waste, such as tissues, organs, body parts, and body fluids that are removed during surgery and autopsy;

5. All discarded sharps (e.g., hypodermic needles, syringes, pasture pipettes, broken glass, scalpel blades) used in patient care or which have come into contact with infectious agents during use in medical, research, or industrial laboratories;

6. Contaminated carcasses, body parts, and bedding of animals that were exposed to pathogens in research, in the production of biologicals, or in the in vivo testing of pharmaceuticals;

7. Other waste determined to be infectious by the facility in its written policy.

(2) Infectious and hazardous waste must be segregated from other waste at the point of generation (i.e., the point at which the material becomes a waste) within the facility.

(3) Waste must be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging must provide for containment of the waste from the point of generation up to the point of proper treatment or disposal. Packaging must be selected and utilized for the type of waste the packaging will contain, how the waste will be treated and disposed, and how it will be handled and transported, prior to treatment and disposal.

(a) Contaminated sharps must be directly placed in leakproof, rigid, and puncture-resistant containers which must then be tightly sealed.

(b) Whether disposable or reusable, all containers, bags, and boxes used for containment and disposal of infectious waste must be conspicuously identified. Packages containing infectious waste which pose additional hazards (e.g., chemical, radiological) must also be conspicuously identified to clearly indicate those additional hazards.

(c) Reusable containers for infectious waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste.

(d) Opaque packaging must be used for pathological waste.

(4) After packaging, waste must be handled and transported by methods ensuring containment and preservation of the integrity of the packaging, including the use of secondary containment where necessary. Plastic bags of infections waste must be transported by hand.

(5) After packaging, waste must be handled and transported by methods ensuring containment and preserving the integrity of the packaging, including the use of secondary containment where necessary.

(a) Waste must not be compacted or ground (i.e., in a mechanical grinder) prior to treatment, except that pathological waste may be ground prior to disposal.

(Rule 1200-6-3-.11, continued)

(b) Plastic bags of infectious waste must be transported by hand.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, and 68-29-105.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Repeal filed May 3, 1995; effective July 17,1995. New rule filed January 7, 1997; effective March 23, 1997. Amendment filed March 22, 2001; effective June 5, 2001. Repeal and new rule filed June 18, 2002; effective September 1, 2002.*

1200-6-3-.12 REFERRAL OF CULTURES TO THE DEPARTMENT OF HEALTH.

(1) It shall be the responsibility of the director of a medical laboratory to submit cultures of those microorganisms designated by the Board to the Department of Health, Laboratory Services for confirmation, typing and/or antibiotic sensitivity, including, but not limited to:

(a) Salmonella species (including S. typhi)

(b) Shigella species

(c) Corynebacterium diphtheriae

(d) Francisella tularensis

(e) Brucella species

(f) Mycobacterium species

(g) Legionella species

(h) Plasmodium species

(i) Vibrio species

(j) Clostridium tetani

(k) Listeria species

(l) Listeria monocytogenes, isolated from sterile sites

(m) Francisella species

(n) Yersinia pestis

(o) Escherichia coli O157:H-17

(p) Clostridium botulinum

(q) Haemophilus influenzae, isolated from sterile sites

(r) Neisseria meningitidis, isolated from sterile sites

(s) Streptococcus pneumoniae, isolated from sterile sites

(t) Streptococcus, Group A, isolated from necrotizing fasciitis wound cultures or normally sterile sites

(Rule 1200-6-3-.12, continued)

(2) All cultures shall be accompanied by the following information:

(a) patient's full name, address, age, and sex.

(b) Physician's name and address.

(c) Anatomic source of culture.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-105, and 68-29-107.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Repeal filed May 3, 1995; effective July 17, 1995. New rule filed January 7, 1997; effective March 23, 1997. Repeal and new rule filed June 18, 2002; effective September 1, 2002. Amendment filed September 17, 2003; effective December 1, 2003.*

1200-6-3-.13 PERSONNEL POLICIES. Personnel policies, practices, and procedures that adequately support sound laboratory practice shall be available in written form. A current record shall be maintained on each employee and shall include evidence of current licensure, and a resume of training and experience, competency assessment, annual safety training and annual review of polices and procedures. Employee health records may be maintained in a separate file.

Authority: *T.C.A. §§4-5-202, 4-5-204, and 68-29-105.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Amendment filed December 14, 1981; effective January 28, 1982. Amendment filed April 25, 1985; effective May 25, 1985. Amendment filed July 13, 1990; effective August 27, 1990. Amendment filed February 26, 1991; effective April 12, 1991. Repeal filed May 3, 1995; effective July 17, 1995. New rule filed January 7, 1997; effective March 23, 1997. Amendment filed April 29, 2002; effective July 13, 2002. Repeal and new rule filed June 18, 2002; effective September 1, 2002.*

1200-6-3-.14 PERSONNEL REQUIREMENTS FOR A MEDICAL LABORATORY.

(1) Condition: All laboratories regulated under T.C.A. 68, Chapter 29 shall meet the personnel standards in Chapter 1200-6-1.

(2) Condition: Each laboratory shall designate a medical laboratory director, general supervisor and testing personnel who meet the qualifications of each level and fulfill the listed responsibilities for each level. If so qualified, one (1) individual may serve in more than one (1) position.

(3) Condition: All individuals qualified to perform laboratory tests, including the medical laboratory director, shall possess a current license issued by the Department. Each individual shall be licensed at the highest level for which he qualified and functions. Laboratory procedures shall only be performed by appropriately licensed individuals, or personnel with a current trainee permit.

(4) Standard: An adequate number of qualified testing personnel shall be provided for the volume and diversity of procedures and tests performed, as determined by the Department by on site survey.

(5) A medical laboratory director may direct no more than three (3) laboratories unless authorized by the Board.

(6) The medical laboratory director shall make periodic on-site visits at a minimum of once per month.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-105. 68-29-114, and 68-29-118.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Repeal filed May 3, 1995; effective July 17,1995. New rule filed January 7, 1997; effective March 23, 1997. Repeal and new rule filed June 18, 2002; effective September 1, 2002.*

1200-6-3-.15 SPECIAL REGULATIONS FOR ASTC, BLOOD DONOR CENTERS, AND PLASMAPHERESIS CENTERS.

(1) An exception to the requirements of 1200-6-3-.14 concerning direction and supervision may be made for a licensed Ambulatory Surgical Treatment Center (ASTC) providing the following are met:

(a) Condition: The laboratory is directed by a physician currently licensed in Tennessee.

(b) Condition: The facility employs a licensed technologist as laboratory supervisor.

(c) Condition: The facility participates successfully in an approved proficiency testing program

(d) Condition: The facility is in substantial compliance with laboratory regulations as determined by an on-site survey conducted by a representative of the Department.

(e) Condition: The facility performs only the following procedures: CBC, urinalysis, ABO grouping and Rh typing, Pregnancy tests, Gram's stain, wet mounts and Rh immune globulin testing. Performance of additional procedures will necessitate that the laboratory meet all regulatory requirements.

(2) An exception to the requirements of Rule 1200-6-3-.14 concerning direction, supervision and technical laboratory personnel may be made for Blood Donor Centers and Plasmaphersis Centers providing the following conditions are met:

(a) The laboratory is directed by a physician licensed in Tennessee who possesses a current Tennessee license.

(b) Screening tests for the purpose of determining donor suitability are limited to:

1. Hemogoblin or hematocrit.

2. Total serum protein.

3. Dipstick urine test for glucose and protein.

4. Urine drug screens for opiates and morphine.

(c) The personnel performing the screening tests shall be trained in the performance of these tests, quality control and recordkeeping duties. The Laboratory Director shall have on record at the facility where the "trained personnel" are employed, documentation of training with date(s) of training and signed by the person(s) administering the training. These "training personnel" shall not be required to have a medical laboratory personnel license.

(d) The facility is in compliance with Rules 1200-6-3-.01 through 1200-6-3-.11 and 1200-6-3-.13.

(e) The performance of additional testing that includes but is not limited to donor accessing (ABO, Rh, Antibody Detection and/or identification, STS, HIV, hepatitis tests, ALT, protein electrophoresis, etc.) shall require the facility to comply with Rule 1200-6-3-.14.

(f) The Donor Center/Plasmapheresis Center shall report the results of all positive tests for hepatitis to the Division of Communicable Disease Control of the Department within two (2) weeks after the last day of each month. The report shall contain the name, address, birth date and social security number of the donor and the name and address of the Center.

(Rule 1200-6-3-.15, continued)

(g) Any inquiries and/or complaints referred to the Department in regard to donor selection, bleeding products, etc. will be referred to the U.S. Food and Drug Administration for investigation.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-104, and 68-29-105.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Amendment filed December 14, 1981; effective January 28, 1982. Amendment filed September 30, 1987; effective November 14, 1987. Repeal and new rule filed January 7, 1997; effective March 23, 1997. Amendment filed February 14, 2000; effective April 29, 2000. Amendment filed December 1, 2000; effective February 14, 2001. Repeal and new rule filed June 18, 2002; effective September 1, 2002. Amendment filed August 25, 2003; effective November 8, 2003.*

1200-6-3-.16 ALTERNATE SITE TESTING.

(1) Point of Care Laboratory Testing.

(a) Definition: "Point of Care" laboratory testing is laboratory testing performed by health care personnel/professionals not licensed by the Medical Laboratory Act, T.C.A. §§ 68-29-101, et seq., and is performed outside the duly licensed laboratory and under the auspices of a laboratory required to be licensed by the Department, pursuant to the Medical Laboratory Act.

(b) All point of care laboratory testing must be approved by the Board in accordance with the following guidelines.

1. For those tests determined by the Board to be appropriate for safe and accurate performance in a point of care setting (see waived test list) written notification shall be submitted on forms provided by the Board to the Administrative Office of the Board.

2. For all other tests not included on part 1200-6-3-.16(1)(b)1. above, approval shall be made only through an examination hearing process of the Board.

3. Requests to perform non-waived point of care tests must be submitted in writing and must include at least:

(i) Statement of medical need for performance outside a laboratory setting.

(ii) Analyte and methodology.

(iii) Personnel authority and responsibility.

(iv) Quality assurance protocols.

(v) Maintenance of records.

(vi) Performance and improvement protocols.

(c) The performance of point of care laboratory testing must comply with the following minimum guidelines:

1. Documentation must show that the method used for testing has been approved by the Medical Laboratory Director.

2. Documentation must show that an adequate training protocol, demonstration of competency, and annual in-service with demonstration of competency for each person performing the testing, has been approved by the Medical Laboratory Director.

3. Records shall be retained for at least two (2) years, which show that manufacturer recommendations regarding the performance of quality control were met. Quality control records shall be reviewed by a person with appropriate authority according to an established performance improvement program.

4. Results of point of care laboratory testing must be recorded in an appropriate clinical record and include the identity of the patient, date and time of specimen collection, units of measurement, test location and identity of the analyst performing the test. Such records must be readily retrievable for inspection.

5. The Medical Laboratory Director shall determine the need for establishment of critical values above or below which the results must be verified by the clinical laboratory using a reference method.

6. Written policies and procedures, as approved by the Medical Laboratory Director, shall be available in the laboratory and at all locations where point of care laboratory testing is performed. Such procedures shall be appropriate to the personnel and location performing the testing.

(d) Approval to perform point of care laboratory testing may be granted annually provided all minimum guidelines are met. The criteria for withdrawal of approval to perform such testing shall include but not be limited to:

1. Performance of testing by unauthorized personnel.

2. Failure to comply with the above stated guidelines

3. Unsatisfactory performance on two (2) consecutive or two (2) of three (3) consecutive proficiency test surveys.

4. Failure to comply with other State or Federal guidelines.

5. Deficiencies without an acceptable plan of correction cited by the Tennessee Medical Laboratory Board surveyors upon and on-site inspection of the laboratory.

(2) Physician's Office Laboratories - Physician Office Laboratories (POLs) are exempt from licensure requirements of the Medical Laboratory Act, pursuant to T.C.A. § 68-29-104(2), when the following conditions are met:

(a) The laboratory must be operated by the physician or through his own employees. In a group practice, one (1) physician must be designated to operate the laboratory. "Operated by" means actual supervision and direct responsibility for the performance of the laboratory and its personnel. This includes but is not limited to actual supervision and direct responsibility of quality assurance, quality control, and test management.

(b) The laboratory testing must be limited to the private and personal patients of the physician or group, with the laboratory reports used for the private practice of that physician or group only and maintained in the medical records of the physician's or group's office.

(c) Industrial or company physician practices, student health services and other arrangements in which a licensed physician is responsible for the continuing care of a group of patients on an ongoing basis will be designated to be POLs.

(Rule 1200-6-3-.16, continued)

(3) Screening Programs - Screening programs conducted by for-profit hospitals or nonprofit organizations are exempt from the licensure requirements of the Medical Laboratory Act, pursuant to T.C.A. § 68-29-104(6), when the following conditions are met:

(a) The screening program must be under the direct supervision of a physician licensed in Tennessee. Direct supervision means that a physician will be responsible for quality assurance of the testing performed and review of the results of such testing. The physician is not required to be on site for the screening program event.

(b) The results of the screening program testing must be submitted to the personal physician of the individual being screened or reviewed by the physician responsible for the screening program. During the screening process, the individual being screened must be afforded reasonable privacy and, when required, on-site confidential counseling about the results of the testing.

(c) A written notification to conduct a screening program must be submitted to the Administrative Office for the Medical Laboratory Board, indicating compliance with these rules and providing the following information:

1. Location of testing.

2. Date of testing.

3. Type of tests to be performed and methodology to be used.

4. Name of the licensed physician supervising the screening.

5. Name and address of the for-profit hospital or nonprofit organization conducting the screening.

6. Statement indicating that the testing staff has appropriate training and competency to conduct the testing.

7. Assurance that the for-profit hospital or nonprofit organization is in compliance with Rule 1200-6-3-.11 regarding the handling of infectious and hazardous waste.

(d) A copy of the written notification submitted to the Administrative office must be retained by the for-profit hospital or nonprofit organization conducting the screening program and must be available for inspection at the site of the screening program.

(e) Notification of screening is not required when the for-profit hospital or nonprofit organization is a licensed medical laboratory, provided the laboratory has complied with Rules 1200-6-3-.17 regarding the performance of waived testing and 1200-6-3-.16 regarding point of care testing.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-29-104, and 68-29-105.* ***Administrative History:*** *Original rule filed February 14, 2000; effective April 29, 2000. Amendment filed December 1, 2000; effective February 14, 2001. Repeal and new rule filed June 18, 2002; effective September 1, 2002. Amendment filed May 23, 2003; effective August 6, 2003.*

1200-6-3-.17 WAIVED TESTING.

(1) Definition: "Waived" means those laboratory tests, as defined by the Board, which may be performed by individuals not licensed under the Medical Laboratory Act, and which pose no reasonable risk of harm if performed incorrectly.

(2) Clinical laboratory tests which are designated as waived shall:

(a) be determined by the Board;

(b) be an analyte and/or methodology previously deemed as waived under CLIA; and

(c) apply to any and all testing sites

(3) Clinical laboratories, pharmacies, and other health care facilities licensed by the State of Tennessee who perform waived testing must comply with the following minimum guidelines:

(a) Notification must be provided to the Administrative Office for the Board using Board approved forms and protocols.

(b) Performance of waived testing by a licensed medical laboratory must be approved by a Medical Laboratory Director as defined by the Tennessee Medical Laboratory Act, T.C.A. § 68-29-103.

(c) In the absence of a Medical Laboratory Director as defined by the Tennessee Medical Laboratory Act, T.C.A. § 68-29-103, performance of waived testing must be approved by the physician legally responsible for laboratory testing performed by that health care facility or pharmacy.

(d) Personnel must perform such testing in accordance with manufacturer recommendations, including quality control.

(e) Patient test results must be recorded in a clinical record, to include date and time of specimen collection, units of measurement and identity of analyst performing the test.

(f) The laboratory, pharmacy, or health care facility must identify personnel responsible for performing and supervising the waived testing.

(g) Personnel performing the waived testing must have adequate, specific training and orientation to perform the tests, and must demonstrate satisfactory levels of competence before performing patient testing, and at a minimum, annually thereafter.

(h) Performance of waived testing will be evaluated by Laboratory surveyors at the time of inspection.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-104, and 68-29-105.* ***Administrative History:*** *Original rule filed June 18, 2002; effective September 1, 2002.*

1200-6-3-.18 COLLECTION STATIONS.

(1) Facilities deemed as collection stations shall perform no clinical testing procedures on site.

(2) Collection stations owned and operated by a clinical laboratory licensed under the Tennessee Medical Laboratory Act shall not be required to obtain an individual license.

(3) Collections must submit to the requirements set forth in Rule 1200-6-3-.08, .09, .10, .13, and .14.

(Rule 1200-6-3-.18, continued)

(4) On-site inspections shall be performed per Rule 1200-6-3-.04.

(5) It shall be the responsibility of the owner to notify the Department in writing of a change in the location or physician or owner within fifteen (15) days of the actual change. A replacement license shall be issued by the Department at no cost for the remainder of the calendar year for a new location, director, or owner, provided that in the case of change of directors, the new director is already licensed or is eligible for licensure as a medical laboratory director under the Medical Laboratory Act and the regulations promulgated thereunder.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-104, and 68-29-105.* ***Administrative History:*** *Original rule filed June 18, 2002; effective September 1, 2002.*

1200-6-3-.19 PREPARATORY PORTIONS OF LABORATORY TESTS.

(1) Tennessee Code Annotated, Section 68-29-129 makes it a violation of the law to allow any person to perform "medical laboratory procedures" except individuals licensed and registered under this chapter. For purposes of that section, the words "medical laboratory procedures" include only the non-preparatory portions of any test required to be performed in a medical laboratory. The preparatory portions of the tests, while they must be performed in a facility licensed by the Board, do not require the extensive education and specialized knowledge required for licensure and may therefore be performed by persons not licensed under the Medical Laboratory Act.

(2) The following are considered to be preparatory portions of tests to be performed in a medical laboratory that may be assigned to persons not licensed under the Medical Laboratory Act:

(a) centrifuging, pouring off and preparing specimens for testing.

(b) preparing peripheral smears at bedside or in the laboratory.

(c) staining peripheral smears by automated methods.

(d) loading primary bar-coded specimens on analyzers.

(e) automated process of sorting, decapping, aliquoting and archiving of specimens.

(f) primary inoculation of microbiology specimens.

(3) A medical laboratory director, as defined by T.C.A. § 68-29-103, must approve preparatory portions of tests performed by individuals not licensed under the Tennessee Medical Laboratory Act.

(4) The laboratory must identify personnel responsible for performing preparatory portions of tests and those with responsibility for supervising them.

(5) Personnel performing preparatory portions of tests must have adequate, specific training and orientation and must demonstrate satisfactory levels of competency before performing preparatory portions of tests, and a competency demonstration must be performed at least annually thereafter.

(6) Laboratory surveyors will evaluate preparatory portions of tests at the time of inspection.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-105, and 68-29-129.* ***Administrative History:*** *Original rule filed April 10, 2003; effective June 24, 2003. Amendment filed September 17, 2003; effective December 1, 2003.*